MEDICINES IN HEALTH CARE DELIVERY

MYANMAR

Situational Analysis:

13-23 October 2014

Report prepared using the WHO/SEARO workbook tool for undertaking a situational analysis of medicines in health care delivery in low and middle income countries

November 2014

CONTENTS

1. ABBREVIATIONS

ABC	ABC analysis – method for measuring drug consumption
ADR	Adverse Drug Reaction
AMR	Antimicrobial Resistance
API	Active pharmaceutical ingredient
BHS	Basic Health Staff
CME	Continuing Medical Education
CMSD	Central Medical Supplies Depot
CPD	Continuing Professional Development
DG	Director General
DIC	Drug Information Centre
DRA	Drug Regulatory Authority
DSO	Drug Supply Organisation
DTC	Drug and Therapeutics Committee
GDP	Good Dispensing Practice
EDL	Essential Drug List
EML	Essential Medicines List
FDA	Food and Drug Administration
GPP	Good Prescribing Practice
HOD	Head of Department
IPD	In-patient Department
MAMS `	Myanmar Academy of Medical Sciences
M&E	Monitoring & Evaluation
MMA	Myanmar Medical Association

MMC	Myanmar Medical Council
MOH	Ministry of Health
MPF	Myanmar Pharmaceutical Factory
MRA	Medicines Regulatory Authority
NDP	National Drug Policy
NF	National Formulary
NGO	Non-Governmental Organisation
NHP	National Health Policy
NMP	National Medicines Policy
OPD	Outpatient Department
OTC	Over-the-Counter
PBPT	Problem-based Pharmacotherapy
PHC	Primary Health Care
PV	Pharmacovigilance
QA	Quality Assurance
RHC	Rural Health Centre
RUM	Rational Use of Medicines
SOP	Standard Operating Procedures
STG	Standard Treatment Guidelines
TOR	Terms of Reference
TRM	Traditional Medicine
VEN	Vital, Essential, Non-essential – method for classifying drug importance
WHO	World Health Organization

2. EXECUTIVE SUMMARY

2.1. Introduction

A situational analysis was conducted in Myanmar during 13-23 October 2014. The Terms of Reference were to examine medicines in health care delivery with respect to medicines supply, selection, use, regulation and policy. It was agreed that the WHO/SEARO workbook tool would be used and that a team of government officials, led by the Essential Drug Program of the Medical Care Division in the Department of Health, facilitated by WHO/SEARO, would conduct the situational analysis.

The team members consisted of:

Dr Kathleen A Holloway, Regional Advisor Essential Drugs & Other Medicines, WHO/SEARO
Dr Thida Hla, Deputy Director, Essential Drug Program, Department of Health, MOH, Nay Pyi Taw
Dr Soe Naing, Director of Central Medical Sub Supplies Depot, Mandalay
Dr Shin Hnaung, Pharmacology Dept., University of Medicines II, Yangon
Dr Thinzar Theik, Department of Food and Drug Administration, MOH, Nay Pyi Taw

The programme involved meetings with all the major government departments and other stakeholders involved in the management of medicines and visits to health facilities in two regions. A detailed program can be seen in section 3. Due to a security alert in Taunggi in Shan state, the visits to this state were rescheduled to occur in Mandalay region. During the visits to public health facilities and private pharmacies, drug stores were visited to collect data on stock availability for 22 selected essential drugs and drug management, outpatient dispensaries were visited to do a prescription audit, wards were visited to review in-patient drug management, and staff were interviewed to identify health and health care factors affecting drug management.

A one-day national stakeholder workshop was held on 22 October 2014 where findings were discussed and recommendations developed. The participants list can be seen in section 12. The findings were presented on behalf of the team by Dr Holloway, WHO/SEARO. Group work was done by participants to develop recommendations in the areas of medicines supply, selection, use, regulation and policy.

The words “medicine” and “drug” are used interchangeably in this report.

2.2. Medicines Supply

Since 2011 the drug supply has dramatically changed from a centrally controlled "push" system to a decentralized "pull" system and government medicines expenditure has increased from less than 0.2 USD/person/year to about 3 USD/person/year. This has resulted in greatly improved drug availability and increased patient attendance. Availability of key essential drugs was 75-80% in hospitals and 59% in rural health centres (RHCs) and sub-RHCs. The reason for non-availability was generally non-use and therefore non-purchase – which accounted for lower apparent availability at RHCs and sub-RHCs simply because they did not treat non-communicable diseases.

Unfortunately, the infrastructure to manage an efficient decentralized procurement system is lacking, with a lack of pharmacists in regional/state health directorates and a lack of capacity to manage technical specifications of tenders, undertake quantification, etc. Furthermore, there are now no economies of scale, since all hospitals with more than 200 beds and all states and regions are purchasing 6-monthly as opposed to central annual procurement. There appears to have been no discussion about which functions may be centralized (e.g. price negotiation, selection of pre-qualified suppliers) and which functions may be decentralized (quantification, ordering, purchase) so as to achieve both economies of scale and an efficient "pull" system.

Since the decentralized system started, emergency orders are still being processed by the Central Medical Supplies Department (CMSD), although it is unclear what their future role will be in procurement and distribution. Since the CMSD has the greatest capacity with regard to procurement, quantification, stock management and distribution, it would be a shame if their skills were not fully utilized. Unfortunately, an electronic drug management information system has not been established and insufficient pharmacists are involved in the decentralised procurement and stock management system.

Recommendations were to:

- Establish harmonised, functional, electronic drug management information system, to monitor consumption, stock-out, expiry which is necessary to improve quantification:
    - start centrally/regionally and then extend to district/township level,
    - employ a data-entry staff for this purpose at each hospital and district/township.
- Employ at least one pharmacist in stock management at regional health offices and district/township hospitals.
- Train staff in monitoring medicine consumption and quantification.
- Develop policies to better manage drugs and contain costs in the new decentralised procurement system:
    - Review and clarify the roles of the public (Myanmar Pharmaceutical Factory and CMSD) and private sectors in procurement and supply. This would include consideration of what functions should be done centrally (e.g. price negotiation, and prequalification of suppliers and products) and what functions locally by hospitals, regions and states. This may need discussion between the MOH, Ministry of Industry and Ministry of Trade/Commerce and could be done by the Additional Health Committee, chaired by the Vice President.

- Review the drug management system with regard to the push and pull systems, double book-keeping system (for CMSD and local procurement) and in-patient ward management of drugs.

2.3. Medicines Selection

The national Essential Medicines List (EML) 2010 contains 341 drugs divided into those recommended for use at tertiary level and those for use at other levels and also including essential and complementary categories for both groups. It is currently being updated and a national workshop, supported by WHO, was held to revise it, but it has not yet been approved by MOH. As previously recommended, the new EML will have medicines categorized by level of user. However, the inclusiveness and transparency of the process are not clear since some workshop participants requested a further national workshop to finalize the EML.

Government policy is that that EML drugs should be used in the public sector and, even following decentralization and local purchase, procurement of EML drugs was over 90% in the CMSD (mostly supplying lower level facilities) and 70-84% in tertiary hospitals. Previous recommendations to form a Drug and Therapeutic Committee in every hospital to provide guidance on what non-EML medicines may be purchased and to monitor compliance have not been followed. This may become increasingly important as hospitals get used to undertaking local purchase and as more and more products become available in Myanmar.

Recommendations were to:

- Revise the Essential Medicines List (EML) (in process):
  - include drugs for all levels of care;
  - classify each drug according to therapeutic class and level of care (both facility level and prescriber level);
  - have wide representation of specialists, pharmacologists, generalists and pharmacists, and transparent process to improve acceptance.
- Implement the revised EML:
  - Consider policy to ensure that most local procurement (e.g. 80% at tertiary level and 90% at township level) consists of EML drugs;
  - Ensure all providers are sensitized/trained on the EML;
  - Monitor compliance to the EML (through consumption analysis and prescription survey).
- Establish a transparent system to review all requests for non-EML drugs:
  - Drug and Therapeutic Committees in each district and tertiary hospital could consider such requests.

2.4. Medicines use

Consumption of medicines has greatly increased since 2011, in line with increased government expenditure on medicines. The average number of drugs prescribed per patient in public hospitals was 2.7-2.8 in 2011 but 3.2-3.3 in 2014. Despite the change from central to local purchase, compliance with the EML was high, the percentage of prescribed drugs belonging to the EML being 75-89% in the public sector as compared to 54% in the private sector. The percentage of drugs prescribed by generic name was 54-73% in the public sector and 26% in the private sector. Irrational use of medicines remains a very serious problem. The percentage of upper respiratory tract infection cases treated with antibiotics was very high in all facility types being 73-92%. Vitamin use was also high, with 39-57% of patients being treated with vitamins in the public sector and 23% in private pharmacies.

There is little monitoring of medicines use and little implementation of policies to promote rational use of medicines, as was found in 2011. There are national standard treatment guidelines for primary care mainly aimed at paramedical workers but they appear to be little used by doctors working in primary care. There are guidelines for secondary care under development by the Myanmar Academy of Medical Science in collaboration with the Myanmar Medical Association but it is uncertain that MOH would adopt these as national guidelines. The discipline of clinical pharmacology is still not developed but the University of Pharmacy has established a post-graduate course on clinical pharmacy. Continuing medical education is adhoc for most practitioners, some refresher training being provided by MOH for public sector prescribers and some by the Myanmar Medical Association for private GPs but there appears to be little focus on prescribing. Hospitals only have procurement committees, not drug and therapeutic committees (DTCs), and public education campaigns on the safe and prudent use of medicines have not been conducted.

Recommendations were to:

- Monitor medicines use:
    - Include prescription audit using diagnosis, which would require that all out-patient registers have diagnosis and medicines recorded;
    - Identify specific inappropriate practices that you want to change (e.g. overuse of antibiotics in upper respiratory tract infection) in order to target interventions to these practices;
    - Should be done by all teaching hospitals and State/Regional health offices.
- Develop National Standard Treatment Guidelines (STGs):
    - Cover secondary as well as basic primary care;
    - Incorporate the activities of the Myanmar Academy of Medical Sciences to develop STGs;
    - Disseminate to every doctor and incorporate into continuing medical education (CME) and undergraduate education.
- Establish Hospital Drug and Therapeutic Committees (DTCs):
    - Require them to monitor drug use, encourage CME, and report annually on activities to MOH;
    - Pharmacists can act as DTC secretaries and implement DTC decisions.

- Review hospital in-patient dispensing procedures:
  - Develop a printed form in which the nurse must sign for each dose of each medicine given, as used in Pyin Oo Lwin general hospital.
- Undertake public education on the prudent and safe use of medicines:
  - Undertake public education campaigns which could be spread through Community Health Workers and the media;
  - Include core pharmaceutical messages e.g. *Antibiotics are not needed for simple coughs & colds.*
- Strengthen continuing medical education (CME) with regard to medicines use:
  - Myanmar Medication Association and Myanmar Medical Council could develop a credit system for CME;
  - Incorporate prescription audit and feedback and ethics into CME;
  - Develop the disciplines of clinical pharmacology and clinical pharmacy.
- Consider establishing a national drug information centre:
  - To provide prescribers with independent information.

2.5. Medicines Regulation

Since 2011 the Myanmar Food and Drug Administration (FDA) has been upgraded from a Division under the Department of Health to a full department under the MOH with its own Director General. This has led to an increase in the number of posts and recruitment is now under way. The pharmaceutical sector continues to grow, with now over 17,000 allopathic drug products registered, 8 manufacturing units, 170 importers/wholesalers and over 10,000 drug retail pharmacies, to be managed by 392 staff. Due to under-staffing and lack of staff capacity the FDA has great difficulty to fulfil all its obligations. The national drug testing laboratory is now testing over 1000 drug samples per year, of which 3-5% fail and a current project is establishing mini-labs in all states and regions. In addition there are 12,000 traditional medicines registered - all for OTC use. Unfortunately post-marketing surveillance is suboptimal and no ADRs have been reported in recent years, drug registration is not stringent enough so allowing too many products on the market, there is no actively used OTC list and monitoring of drug promotional activities is weak.

Recommendations were to:

- Strengthen the Department of the Food and Drug Administration (FDA):
  - Recruit more inspectors and pharmacists – 1 pharmacist per township;
  - Develop Standard Operating Procedures (SOPs) and guidelines for all procedures;
  - Train staff in various regulatory functions including dossier evaluation for drug registration and inspection of manufacturing plants for Good Manufacturing Practice;

  - Amend current regulations to allow more punitive actions (partially done through Amendment of National Drug Law in April 2014).

- Strengthen national laboratory capacity in quality testing of drugs:
  - Establish functional laboratories in Mandalay and Yangon and increase the number of samples tested per year;
  - Expand the minilab system to test more samples and more drugs in every state and region;
  - Develop Standard Operating Procedures (SOPs) and guidelines for all procedures.
- Strengthen post-marketing surveillance:
  - Improve the combatting of illegal substandard, spurious, fake, falsified, counterfeit drugs, particularly in the border areas;
  - Establish a unit to coordinate pharmacovigilance activities and sensitize prescribers to report adverse drug reactions;
  - Start monitoring of drugs prices and consider price controls for essential drugs.
- Establish more drug schedules:
  - Over-the-Counter (OTC) drugs;
  - Drugs for use in tertiary referral hospitals only with availability only from special pharmacies, such as oncological drugs, new antibiotics (such as is currently the case for controlled drugs).
- Strengthen the drug registration process:
  - Have a transparent process with stronger criteria, stricter application of criteria, and review of all products by the technical advisory committee;
  - Will help to reduce an excessive number of products being registered for some molecules.
- Consider establishing a unit to monitor drug promotional activities:
  - Would allow more active monitoring of adverts in the market;
  - Could introduce a requirement for all manufacturers to declare expenses on marketing.

2.6. Medicines Policy and Coordination

The national drug policy, coordination and structure remain similar to the situation in 2011. The FDA has been upgraded and more posts sanctioned but the Essential Drug Program (EDP) remains the same. Many objectives of the 2001 national drug policy remain unfulfilled and many policies to promote rational use of medicines and to monitor medicines use are not implemented by any MOH department or unit. There is a high level committee – the Additional Health Committee - which is chaired by the vice-president, with representation from many Ministries, but it does not seem to have discussed many problem pharmaceutical policy issues or the national drug policy.

Recommendations were to:

- Organize high level drug policy discussions in the Additional Health Committee, which is chaired by the vice-president, with representation from many Ministries. Examples of policies for discussion include:
    - Review and clarify the roles of the public (MPF and CMSD) and private sectors in procurement and supply, including what functions should be done centrally (e.g. price negotiation, and prequalification of suppliers and products) and what functions locally by hospitals, regions and states and what extra human (e.g. pharmacists) and financial infrastructure are needed.
    - Review/streamline fiscal requirements with regard to local procurement and auditing. For example, overworked nurses currently have to operate 6 stock books for in-patient ward management of drugs.
    - Review the trade rules of competition with regard to licensing of pharmacies and registration of new products for molecules where there are already many products on the market. Allowing the unlimited licensing of shops and products results in a heavy regulatory burden for the FDA and compromise patient safety.
    - Review the national drug policy and develop an implementation plan and budget.
- Strengthen the Myanmar Essential Medicines Project (EDP) to be the Executive Division in MOH to implement the decisions of the Additional Health Committee within the MOH:
    - To coordinate action between all MOH divisions and different Ministries;
    - To be responsible for rational use of drugs: EML, STGs, DTCs, monitoring drug use, CME, Drug Info Centre, public education;
    - To liaise with universities to provide students to collect information needed by the MOH, as part of their research studies;
    - To review/update the National Medicines Policy to be more specific and to include an implementation plan, budget and time line.

3. PROGRAMME AGENDA

Day	Date	Time	Places visited
1	Mon 13/10.14	Am	Orientation of assessment team and visit to WHO country office
		Pm	Visit to North Oakkalapa Tertiary Hospital, Yangon
2	Tues 14/10/14	Am	Visits to University of Medicines I (Pharmacology) Yangon; Myanmar Medical Association; Myanmar Academy of Medical Science
		Pm	Visits to CMSD Yangon
3	Wed 15/10/14	Am	Visits to University of Pharmacy Yangon; North Dagon Township Hospital
		Pm	Visits to RHC and Sub-RHC in East Dagon township
4	Thurs 16/10/14	Am	Yangon – Nay Pyi Taw
		Pm	Visits to Dept. of Health; Dept. of Traditional Medicines, Nay Pyi Taw
5	Fri 17/10/14	Am	Nay Pyi Taw – Mandalay; visit to Mandalay Regional Health Dept
		Pm	Visits to Mandalay 300-bedded teaching hospital and CMSSD Mandalay
6	Sat 18/10/14	Am	Visits to Pyin Oo Lwin general hospital in Mandalay region
		Pm	Visits to 2 private pharmacies in Pyin Oo Lwin town in Mandalay region
7	Sun 19/10/14	Am	Visits to Patheingyi Township Hospital, Mandalay region
		Pm	Visits to RHC and Sub-RHC in Patheingyi Township; Mandalay - Nay Pyi Taw
8	Mon 20/10/14	Am	Preparation for the workshop
		Pm	Preparation for the workshop
9	Tues 21/10/14	Am	Visit to private pharmacy in Nay Pyi Taw
		Pm	Visit to Department of Food and Drug Administration
10	Wed 22/10/14	Am	National workshop
		Pm	National workshop
11	Thurs 23/10/14	Am	Nay Pyi Taw - Yangon
		Pm	Debriefing with WHO

4. MEDICINE SUPPLY

4.1 Responsible Agents/Departments

Function/ Organisation	MOH	Other Agency	Name of Agency/MOH Department
Selection	√		Essential Drug Program, Dept. of Health
Quantification	√		Central Medical Supplies Dept (CMSD) centrally and also regional & state health authorities and all hospitals with more than 200 beds
Procurement	√		Central procurement by CMSD and local procurement by regional & state health authorities and all hospitals with more than 200 beds
Pricing	√	√	Ministry of Commerce in collaboration with the Myanmar Pharmaceutical Medical Products and Entrepreneur Association, especially for imported drugs
Storage	√		Health facilities and CMSD/MOH
Distribution	√	√	CMSD and local wholesalers as per health facility demand
Monitoring & evaluation	√		Dept. of Health State and regional health authorities are supposed to monitor management of medicines in public health facilities

The Supply Chain Management System (SCMS), Management Sciences for Health, supported by PEPFAR/USAID is currently supporting supply chain management in 3 states.

4.2. Drug availability

Very few reports have published recent data on the availability of essential medicines. The situational analysis of 2011 found that government expenditure on essential medicines was less than 0.2 USD/per/year, and that many drugs were out of stock and that in some facilities the CMSD shelves were nearly completely empty. A recent baseline survey of the national supply chain done by MSH (Tolliver 2014) in 2013 found that 56% of facilities experienced a stock-out and that availability of tracer essential drugs was 74%, there being a stock-out of 26% of tracer medicines. However, only two of the tracer items were classed as essential drugs and availability of these was 75% (stock-out rate of 25%).

By 2014, government health expenditure on essential medicines has increased to about USD 3/person/year and nearly all health workers said that availability was much better since decentralization has occurred with local procurement by health facilities. Most health facilities did not complain of any stock-outs and most patients were receiving all the medicines prescribed. Table 4.2.1 show some data on stock availability and stock-out. In N. Oakkalapa tertiary hospital in Yangon, the hospital was not providing outpatient drugs, rather there was a private pharmacy in the hospital compound dispensing all the OPD prescriptions and it was observed that 96% of all prescribed drugs were dispensed. In the other health facilities, the % of prescribed drugs dispensed could not be estimated as data was collected from OPD patient registers, rather than patient prescriptions as there were too few patients in the OPD at the time of the visit to collect data from patient prescriptions.

The % of key EML drugs available was based on a list of 22 drugs chosen by the team from the EML, consisting of: caps/tabs of amoxicillin, ciprofloxacin, cotrimoxazole, metronidazole, albendazole or mebendazole, amlodipine, enalapril, ferrous/folic acid, glibenclamide, metformin, paracetamol, ibuprofen, omeprazole, diazepam, frusemide; oral rehydration solution; salbutamol nebulizer solution; antibiotic eye/ear drops; benzyl benzoate lotion; atropine injection; hydrocortisone injection and normal saline intravenous fluid.

Table 4.2.1: Summary of EML* drug availability from observation and record review in the public health facility surveys:

Public Referral Hospitals	1	2	3		Average
% items out of stock	33%	?	14%		24%
% key EML drugs available	60%	90%	91%		80%
Public Township Hospitals	1	2			
% items out of stock	26%	12%			19%
% key EML drugs available	58%	92%			75%
Public primary health care centre	RHC 1	sub-RHC 1	RHC 2	sub-RHC 2	
% items out of stock	10%	32%	24%	5%	18%
% key EML drugs available	61%	49%	75%	50%	59%

* Belonging to the national EML or the provincial / hospital formulary in decentralized systems

It can be seen that availability of key essential medicines was 59-80%. The reason for non-availability was mostly non-purchase due to non-use. In particularly the lower availability of key essential drugs at RHCs and sub-RHCs was due to non-use of many of the key essential medicines, particularly those used for non-communicable diseases. The availability of key essential medicines at RHC level and above was notably better in the Mandalay region (75-91%) as compared to the Yangon region (49-61%). Virtually all the essential drugs were available at the private pharmacies. Each health facility had a number of non-EML drugs and followed its own list. Some facilities were unable to say what the total number of items purchased was, so the % of items out of stock could not be calculated.

The increase in government drug expenditure and drug availability has been associated with an increase in annual patient attendance from 3,659,822 in 2011 to 4,166,338 in 2012 (MOH 2014) and it was stated that the increase has continued in 2013 and 2014. Observation during the situational analysis also noted that on average doctors were seeing about 30 patients per day in 2014 as compared to 10 patients per day in 2011 (Holloway 2011).

4.3 Annual aggregate data of medicines distribution / consumption

Tables 4.3.1 and 4.3.2 show aggregate purchase data for the year 2013 for the CMSD and 3 tertiary referral hospitals, respectively. The aggregate data was extracted from manual records and typed into an excel spreadsheet for analysis. During the process a large amount of manual recording was done and as a result there may be some inaccuracies. Antiseptic solutions have been excluded from this analysis.

Table 4.3.1: ABC analysis of top 24 items in 2013 – CMSD national level

Source of data (government department/organization): CMSD purchase data

Rank	Item Name/Strength	Value (Kyat)	EDL
1	Anti-Rabies Vaccine(ARV)	2,429,800,000	√
2	OC Pills	2,142,000,000	√
3	Depo provera inj: 1ml	1,105,228,800	√
4	Ceftriaxone Inj: 1000mg 10ml	1,040,000,000	√
5	Amoxycillin/Clavulinic acid - 375 mg	961,640,000	√
6	Cefotaxime inj:1G 10ml	933,600,000	x
7	Anti Snake Venon Vaccine (Polyvalent)	816,000,000	√
8	Flucloxacillin Cap: 250mg	597,500,000	√
9	Mannitol Infusion 200ml	585,000,000	√
10	Dental Cartridge	434,000,000	√
11	Water for Inj: 100 x 5ml	351,600,000	√
12	Misoprosol	29,600,0000	√
13	Cycloserine 250mg	257,256,000	√
14	Sodium Chloride 0.9% Infusion 500ml	217,800,000	√
15	Gentamycin Inj: 80 mg, 2ml	208,000,000	√
16	Dextrose 5 % in water 500ml	198,000,000	√
17	Clindamycin 150mg	194,000,000	√
18	Tranexamic Acid 250 mg/5ml	192,004,000	√
19	Dextrose 5% in Sodium Chloride 0.9% Infusion 500ml	189,000,000	√
20	Sulbactum/Cefopyrazone	176,561,000	x
21	Gentamycin Eye and Ear Drop (0.3%)	175,009,000	√
22	Efavirenz (EFV) 600mg	173,320,000	x
23	Omeprazole 20 mg	156,000,000	√
24	Ringer Lactate Inj 500ml	148,500000	√
	Top 24 medicines	13,977,818,800	
	Total budget for all 114 items distributed by CMSD in 2013: Kyat 16,877,326,700		
	Top 24 (21%) items cost 82% budget; Antibiotics 32%, Vitamins 1%, EML drugs 91%.		

Table 4.3.2: ABC analysis of top 24 items – 3 tertiary level hospitals

Source of data (government department/organization): Hospital purchase data 2013

	N. Oakkalapa, Yangon			Mandalay 300-bedded			Pyin Oo Lwin 300-bedded		
#	Item Name	Kyat	EDL	Item Name	Kyat	EDL	Item Name	Kyat	EDL
1	Amoxycillin + Clavulanic Acid 1.2 G Inj	89460000	√	Amoxicillin + Clavulanic Acid 1.2 G Inj	31950000	√	Ceftriaxone 1 G Inj	34630000	√
2	Cefoperazone + Sulbactam 1 G Inj	39200000	x	Flucloxacillin+ Amoxicillin Inj	17290000	x	Benzyl Penicillin Inj	22893750	√
3	Amoxycillin + Flucloxacillin 500mg Inj	36400000	x	Pantoprazole Inj	14400000	x	Normal Saline 500ml IV	17485940	√
4	Normal Saline 500ml IV	29400000	√	Povidone Iodine 120 ml solution	13500000	√	Metronidazole 100ml Inj	11200000	√
5	Levofloxacin 500mg Inj	23400000	x	Ceftriaxone 1G Inj	11466000	√	Pantoprazole 40mg Inj	10805000	x
6	Povidone Iodine 10%, 5 Lt sol	20000000	√	Amoxicillin + Clavulanic Acid 625 mg Tab	10600000	√	Flucloxacillin + Amoxycillin Inj	7280000	x
7	Ceftriazone 1 G Inj	18850000	√	Cefoperazone+Sulbactam 2G Inj	7200000	x	Ceftazidime 1 G Inj	7001617	√
8	Amoxycillin + Clavulanic Acid 625mg Tab	16785000	√	Normal Saline 500ml IV	7200000	√	Albumin IV	5690000	√
9	Omeprazole 40mg Inj	15520000	√	Cefoperazone+Sulbactam 1G Inj	6800000	x	Ringer Lactate 500ml IV	5350000	√
10	Ceftazidine 1G Inj	15300000	√	Amoxicillin + Clavulanic Acid 0.6 G Inj	6690000	√	Tramadol Inj	4800000	√
11	Amoxycillin + Flucloxacillin Cap	15120000	x	Metronidazole Inj	6510000	√	Mannitol Inj	4460000	√
12	Ceftriaxone + Sulbactam 1.5g Inj	14450000	x	Flucloxacillin + Amoxacillin Tab	5760000	x	Flucloxacillin + Amoxycillin Cap	4320000	x
13	Propofol 20ml inj	13511630	√	Cefotaxime Inj	5625000	x	Water Inj	3792000	√

	N. Oakkalapa, Yangon			Mandalay 300-bedded			Pyin Oo Lwin 300-bedded		
#	Item Name	Kyat	EDL	Item Name	Kyat	EDL	Item Name	Kyat	EDL
14	Streptokinase Inj	13400000	√	Ringer Lactate IV	5400000	√	Tranexamic acid Inj 250mg	3702500	√
15	Dobutamine 250mg Inj	12756000	√	Salbutamol nebules 2.5 mg	5040000	√	Cefuroxime 750mg Inj	3422500	√
16	Tramadol 100mg inj	11900000	√	Artesunate Inj	4760000	√	Ventolin Nebulizer	2775980	√
17	Metronidazole Inj	11480000	√	Dobutamine Inj	4720000	√	Cephalexim 500mg Cap	2522000	√
18	Vecuronium 4mg Inj	10800000	√	Cephalaxin 750 mg Tab	4716000	√	Pantoperazole Tab	2160000	x
19	Imipenam+ Cilastatin Inj	10545000	√	Povidone Iodine 15 ml solution	4200000	√	5% Dextrose 500ml IV	2140000	√
20	Dextrosaline 500ml IV	10290000	√	Medazolam Tab	4050000	√	Oxytocin 5 IU Inj	2110600	√
21	Ringer Lactate IV	10045000	√	Isoflurane 250 ml Inj	3658000	√	Ofloxacin 200mg Tab	2052000	√
22	Cefotaxime 1G Inj	9715000	x	Levofloxacin Inj	3600000	x	Chlorosuxcilin Inj	2045000	x
23	Cefixime 200mg Cap	9676000	√	Lactulose	3528000	√	Isoflurane 100ml Inj	1988000	√
24	Anti-Tetanus Toxoid Inj	8330000	√	Cephalaxin 500 mg Tab	3350000	√	Bupivacaine heavy Inj	1944600	√
	Top 24 items	466,333,630		Top 24 items	192,013,000		Top 24 items	166,571,487	
	Total budget	814,493,055		Total budget	299,803,035		Total budget	229,145,955	
	Top 24 items (11%) consume 61% budget; Antibiotics 51%, vitamins 0.7%; EML drugs 70%			Top 24 items (11%) consume 65% budget; Antibiotics 47%, vitamins 2%; EML drugs 72%			Top 24 items (10%) consume 73% budget; Antibiotics 47%, vitamins 2%; EML drug 84%		

The system of procurement and distribution was in transition during 2013, going from a system where CMSD supplied all medicines centrally to a system where hospitals undertook their own local procurement. The exact proportion of drugs supplied to hospitals from the CMSD and procured locally by the hospitals during this period is unknown, but the view of the hospital staff was that perhaps half of the drugs had been supplied by the CMSD to the hospital. The hospital procurement data, shown in table 4.3.2, does not include data on the medicines supplied by the CMSD to the hospitals, as such drugs were supplied free.

However, the budgetary allocation for medicines are as follows; (Kyats in million)

1. North Okkalapa General Hospital 1,200 (in year 2013-14) 3241.5 (in year 2014-15)
2. 300 bedded Mandalay Teaching Hospital 450 (in year 2013-14) 433 (in year 2014-15)
3. Pyin Oo Lwin General Hospital 450 (in year 2013-14) 520 (in year 2014-15)

Comparison of budgetary allocation for 2013-2014 with the procurement data shown in table 4.3.2, would indicate that the percentage local purchase in 2013 was 67% in North Okkalapa General Hospital, 67% in 300 bedded Mandalay Teaching Hospital, and 51% in Pyin Oo Lwin General Hospital. These figures are approximate since they assume complete expenditure of allocated budget and the time frame for the ABC analyses was 2013 while that for allocated budget was 2013-2014. Since relatively large amounts were still being supplied by the CMSD, the overall top 24 drugs by value in each hospital may be slightly different.

The data show that in all cases the top 10-20% of items consumed 60-80% of the budget. A large proportion of the budget was spent on antibiotics. In the CMSD, only 9% of the budget was spent on non-EML drugs but in the three hospitals about 16-30% of the budget was spent on non-EML items. This use of non-EML medicines is similar that that found by the recent SCMS/MSH survey of 2013 (Tolliver 2014). The non-EML items were mostly 3rd generation cephalosporins and combination products of amoxicillin with flucloxacillin or a 3rd generation cephalosporin with sulbactam. Pantoprazole tablets and injections also featured in the top 24 drugs in two hospitals. This data show that the hospitals are starting to procure non-EML medicines and this tendency is likely to increase in the future unless there is a clear central policy to use EML drugs and compliance is monitored. Since there are 3rd generation cephalosporins and omeprazole on the EML, justification should be given for using non-EML cephalosporins and pantoprazole, which consume a large part of the budget. Collation and analysis of such aggregate data can give an indication of where more detailed monitoring of medicines use should be directed. It was also noticed that small quantities of monotherapy artesunate and artemether tablets and injections were also procured by two tertiary hospitals in 2013 and that although these items still belong to the 2010 EML, there is international effort to ban the use of these products due to the problem of resistance. Unlike in 2010, multivitamins were not amongst the top 24 drug by value in CMSD procurement.

The top 15 causes of mortality in 2012 (MOH 2014) were as below in order:

HIV/AIDS, septicaemia, injuries, fetal malnutrition and low birth-weight disorders, liver disease, respiratory disease, intrauterine hypoxia and birth asphyxia, heart failure, respiratory tuberculosis, intracranial haemorrhage, other heart disease, intracranial injury, malaria, pneumonia, and stroke.

The top 15 causes of morbidity in 2012 (MOH 2014) were as below in order:

Injuries, complications of pregnancy and delivery, delivery, infectious diarrhoea, other viral diseases, other pregnancies with abortive outcome, gastritis and duodenitis, malaria, cataract, acute upper respiratory

tract infections, pneumonia, other perinatal conditions, toxic effects of non-medical substances, bone fractures, and appendicitis.

The top drugs by value as seen in the CMSD and 3 hospitals contain many antibiotics and intravenous fluids, which is consistent with the treatment of the top conditions causing mortality and morbidity - infections and injury. Anti-rabies vaccine and anti-snake venom feature amongst the highest drugs by value, probably due to high purchase prices, since rabies and snake-bite do not feature as major causes of death or mortality. Only one anti-retroviral is amongst the top 24 drugs in CMSD and no anti-retrovirals are in the top 24 drugs of the 3 hospitals, which is surprising given that HIV/AIDS is the top cause of mortality and it be that anti-retrovirals are supplied by a separate parallel system.

4.4. Drug Procurement

4.4.1. National Public Sector Drug Procurement

National central procurement is under transition. In 2011 all procurement was done by the CMSD centrally and in 2014 almost all procurement was being done locally by hospitals with more than 200 beds and by regional and State Health Authorities. Nevertheless, it has taken some time to make the change over and in 2013 about half the medicines were supplied by the CMSD and half locally purchased and in 2014 some items are still being supplied “free of charge” to some hospitals and regional and State health authorities upon request. It is unclear what the future role of the CMSD will be in medicines procurement. Some people stated that the CMSD would concentrate on medical equipment in the future. Vertical disease control programs operate their own procurement and distribution systems.

CMSD procurement is managed in virtually the same way as in 2011. Essential medicines which can be manufactured by the government-owned Myanmar Pharmaceutical Factory (MPF) are procured from them by the CMSD as preference is given to the MPF over other manufacturers. Other CMSD procurement is done by annual national in-country tender through national importers and suppliers. In 2011 about 70% of drugs procurement by the CMSD came from the MPF but this proportion is now lower as the MPF has not been able to manufacture the medicines required by health facilities in the required amounts in a timely way. All purchase is in Kyat from wholesalers and importers. The only exception to this is purchase from the government-owned MPF by the CMSD.

The CMSD follows procurement SOPs. Tendering operates by a manual 2-envelope system, one envelope containing the price quotation and the other technical specifications. Technical specifications include a 5% performance guarantee deposit (part or all of which will be forfeited for default, late delivery, defective products, etc.), provision of a sample, a drug registration certificate, 2 years shelf-life after delivery, and adequate container and packet labelling. Tenderers must also deposit a tender premium, which will be forfeited in the event of failing to proceed with any award granted or reimbursed should no award be given. All payment is in Kyat which prohibits international purchase. The procurement committee for the CMSD decides upon which tenders will be granted and consists of the Director General of the Department of Health Services, the Deputy DG of the Department of Food and Drug Administration, Deputy DG of the Division of Medical Care, the Chief of the CMSD and the Director of Finance within the MOH.

According to the recent SCMS/MSH 2013 survey, the average lead time for the CMSD was very lengthy at 145 days, the delivery time was 105 days, price variance for medicines was 66% above international reference prices and no procured samples had been submitted by CMSD for quality testing (Tolliver 2014).

4.4.2. Provincial/District/Health facility Drug Procurement

Procurement done locally is managed by the Medical Superintendents of hospitals (with more than 200 beds) or the Director of Regional/State Health Authorities (for health facilities with less than 200 beds) and is done 6-monthly. They are supposed to follow the same SOPs as used by the CMSD. Tenders are invited by newspaper and procurement is made from about 20 wholesalers. The procurement committees generally consist of the Minister for Social Welfare (chair), the State or Regional Health Director (who acts as secretary in the case of state or regional procurement), the hospital Medical Superintendent (who acts as secretary in the case of hospital procurement), one specialist from each of the major specialties, the matron (in hospitals), a representative of a district and township hospital (in the case of regional/state procurement), a representative from the local CMSD branch (if available) and a representative from transit camps (in the case of regional/state procurement).

In hospitals the pharmacy staff compiled results from the tender and in one regional health directorate a doctor compiled the results, there being no pharmacist to do this. Provided the suppliers meet the various financial considerations and can produce a certificate of drug registration for each product and a sample, it appears that selection may be on the basis of price and shelf-life. However, the DG of the Department of Food and Drug Administration stated that there had been some fake certificates of drug registration circulating and that many hospitals and regional/state directorates did not have the capacity to distinguish fake from real certificates. Also, it appeared that there was very little capacity in regional/state health directorates and hospitals to evaluate technical specifications of bids. None of the procurement respondents met had sent samples for analysis. Some tendering was done by line item but some was done by lot, which was proving very difficult to manage. For example, one lot system was according to formulation and another lot system by facility type involved. However such lot systems are difficult to operate because some suppliers may only be able to supply some items in a “lot”, not all. Also a lot system for different facility types would involve ordering the same products in different lots and so decreasing quantities and economies of scale with regard to negotiating better prices. One regional director mentioned that priority was given to essential drugs and non-EML drugs may only be purchased if there is sufficient remaining budget.

According to the recent SCMS/MSH 2013 survey, the average lead time for local hospital purchase was 33-35 days, which is much shorter than that for CMSD but was probably that short due to some contracts being awarded on the basis of product availability (Tolliver 2014). However delivery time at 111 days was slightly longer than that for CMSD. It was also mentioned that vendor on-time delivery was 52% (33% early, 14% late) with great variation across states, being 83% in Mandalay, 29% Yangon, 0% in Shan state (Tolliver 2014).

Local purchase by every hospital with more than 200 beds and all regional and state health authorities means that there are no economies of scale. It is likely that the drug prices will be considerably higher in such a system than with a central procurement system. While many people are pleased with the local purchase system, it is much more costly and there appears to have been no discussion on how quality suppliers and drug prices might be negotiated centrally for all local purchase.

Table 4.4.1 compares the CMSD (central) unit price for medicines that were supplied centrally with the unit price for medicines that were procured locally by 3 referral hospitals. As can be seen local unit prices were nearly 90% higher on average than central ones. Such small purchases without sufficient technical input into the procurement process are likely to result in higher prices for poorer quality medicines.

Table 4.4.1: Unit price comparisons between central and local purchases

Drug Name	CMSD unit price	Local unit prices			% greater price of local unit prices compared to central unit prices
		North Oakkalapa Hospital	Mandalay 300-bedded hospital	Pyin-oo-Lwin 300-bedded hospital	
Atropine injection	19	44.9	230	-	1110.5
Amoxiclav 375mg (148-210)*	179*	282	-	282	57.5
Amoxiclav 1.2g inj	1700	2982	-	3550	108.8
Azithromycin 250mg (115-175)*	145*	166	-	225	55.2
Cotrimoxazole 480mg (11-15.17)*	13	12.8	-	13.09*	0.7
Cefotaxime 1g inj	389	670	750	-	92.8
Ceftriaxone 1g inj (975-1730)*	520	725	420	1352.5*	160.1
Dexamethasone 8mg inj	95	111	160	125	68.4
Diazepam 5mg tab	70	9	20	25	-64.3
Diclofenac 50mg tab	5	5.85	5.8	8	60.0
Frusemide 40mg tab	10	-	12.5	10.5	25.0
Gentamicin eye/ear drops (187-450 CMSD & 375-425 Pyin-oo-Lwin)*	318.5*	-	1275	400*	25.6
Levofloxacin 500mg inj	1500	1950	1800	-	30.0
Mannitol inj (610-1950)*	1300	1400	-	1300*	-1.6
Metronidazole inj	320	280	310	280	-3.1
Metronidazole 200mg	7	7.8	9.5	8	35.7
Normal Saline 500ml	495	490	360	535	8.1
Ringer Lactate 500ml	495	490	360	535	8.1
Paracetamol 500mg tab	5	4.6	4	8	60.0
Paracetamol elixir 120mg/5ml (288-900)*	594	325	300	315	-47.1
Average % difference between central CMSD unit prices and unit prices in hospital purchases					89.5

*Price range for unit prices in which case the average was taken.

4.5. Allocation of budget for medicines in the public sector

In 2011 annual per capita government drug expenditure was less than USD 0.2 USD, only 92 out of 341 items on the national EML were procured and drug stocks appeared to last about a month. In 2013, annual per capita government drug expenditure was increased to about 3 USD, and all medicines on the EML were being procured either by the CMSD or by local purchase. The budget allocation in 2013 was done on the basis of 15 lakhs Kyats per hospital bed per year. The Department of Health made clear that this formula was arbitrary and that future allocation would be done on the basis of need. However, the need appears to depend on previous expenditure for medicines and this may vary according to what medicines are

purchased for what price. It is also not clear from this formula what budget is awarded for RHCs and sub-RHCs which have no beds.

4.6. Drug quantification in the public sector

In 2011, CMSD quantification was based on the past 3 year's consumption according to a central budget allocation for each health facility based on the number of beds. However, now the quantification system by the CMSD is unclear because hospitals, regions and states are not buying from them and past demand by hospitals of medicines from CMSD is rapidly changing. It appears that CMSD is only procuring medicines for emergencies and controlled medicines, although some facilities are still ordering many non-emergency and non-controlled items from them. With regard to states, regions and hospitals, quantification is done 6-monthly on the basis of the past 6 month's consumption. There is no electronic drug management information system. The lack of previous reliable data, which in any case did not reflect true need as there were multiple stock-outs, hampers quantification. Many health facilities mentioned sending emergency orders to CMSD about 2-3 times per year. One Yangon hospital mentioned that they sent emergency orders to CMSD 2-3 times per week and one RHC stated that they never sent emergency orders. Nobody appeared to be keeping buffer stock.

4.7. Drug Distribution in the public sector

4.7.1. Drug Distribution from the central national level

In 2011 the CMSD operated a centrally controlled "push" system, whereby a certain quantity of medicines was sent to each facility 6-monthly according to quantities pre-determined by the CMSD, not according to what the health facility demanded. Some facilities complained that they had been sent items they did not want or use. With local procurement in 2014, a "pull" system is operating where drugs are being procured/ordered according to the request of facilities. While procurement was being done 6-monthly by all regions/states and hospitals with more than 200 beds, emergency orders were still being requested from CMSD about 2-3 times per year.

For all purchases done by CMSD, the drugs are stored in a central (Yangon) or branch (Mandalay and Taunggyi) warehouse and distribution contracted out to private transport companies. Since most states and regions do not have their own warehouses, drugs purchased by hospitals, regions and states, are delivered directly by the supplier to the concerned hospital, including township hospitals, from where RHCs and sub-RHCs must order their medicines. Previously, CMSD had supplied all the drugs to RHCs and sub-RHCs but now some medicines are coming from the township hospitals and some from the CMSD still.

There is no electronic management information system so drug stock management using a paper-based system is difficult. The CMSD does not visit health facilities to supervise stock management and it appears that this function is done by the regional/state health directorates for township hospitals and below and by the Medical Care Division within the Department of Health centrally. The CMSD mentioned that they have 300 staff working in Yangon and 60 in Mandalay. They complained that this was not enough, but it is certainly more than any other body in the country.

4.7.2. Drug Distribution between and within health facilities in the public sector

There appears to be some re-distribution of medicines, especially between RHCs, sub-RHCs and township hospitals, particularly when there are short-dated items. Almost every facility had a list on the store wall of all the items with less than 6 months shelf-life in order that these items may be returned to the CMSD or redistributed to a higher level facility or one with a shortage of the concerned medicines. Very few facilities admitted to any expired medicines and this may be because they have had very few items in stock until recently so there has been no time for stock to expire.

The CMSD warehouses were of adequate quality, although they complained of some shortage of space. However, some hospital stores had inadequate space, shelving, temperature, and humidity control. The current system of stock management requires double book-keeping for CMSD supplies and local purchase supplies. This means that every facility has two stock books in the store, one for CMSD and the other for local purchase, often covering the same drugs. In some hospitals, there were six stock books in the wards, two each for the "main store" (room in the ward), the "sub-store" (cupboard in nurses station) and the "daily store" (trolley). This meant one had to check six books in order to find out the stock level of any item. Such a cumbersome arrangement is very time consuming and will lead to poor record keeping and difficulty in reconciling documented and actual stock. Despite all this, stock books and bin cards were often well maintained, if not used for quantification or other analysis.

According to the recent SCMS/MSH 2013 survey (Tolliver 2014), only 35% facilities submitted LMIS reports and only 14% of facilities stocked medicines within pre-decided maximum and minimum levels, although order-fill rates were 101%.

Pharmacists were only employed in hospitals with 200 or more beds and all other facilities below this level relied on nurses, compounders and store keepers to manage drugs. The one regional health authority visited also had no pharmacist to help with quantification for the region and the tendering process. This is unfortunate because pharmacists have much needed skills to manage drugs and each year the University of Pharmacy in Mandalay and Yangon produces 200-250 graduate pharmacists per year of which only 15% find jobs in the public sector.

4.8. Patient Flow in the Health Facilities

The health sector comprises more than 1000 hospitals, of which about half are station hospitals, situated 1-2 per township. There are 325 townships, each with a township hospital, 4-5 rural health centres (RHCs), each of which, in turn, has 4-5 sub-RHCs. A station hospital has 16 beds, a township hospital 25-100 beds, a district hospital 150 beds, and a general hospital 200 or more beds. Paramedical workers staff RHCs and sub-RHCs. Health Assistants of 4 years training staff RHCs and midwives of 1.5-2 years training generally staff sub-RHCs. In addition there are various other cadres, such as lady health visitors of 2 years training who may also prescribe in the RHCs and sub-RHCs. Prescribing in township hospitals and above is done by doctors. Every township hospital is required to have a compounder of 1 years training, but paramedical workers or midwives generally handle medicines at the RHC and sub-RHC level.

Patients register for free, and then go to the general OPD, or the specialist OPD, or the emergency room in hospitals. In RHCs and sub-RHCs, patients immediately see the paramedical prescriber. All medicines are dispensed free of charge in IPD and OPD except in some tertiary hospitals in Yangon where outpatients had to purchase their medicines from a private pharmacy within the hospital compound. In hospitals, patients

had to pay a small fee for diagnostic test, about 1000 Kyat per test, i.e. there was cost sharing for diagnostic tests. Tertiary hospitals also operated some private beds, where patients paid 7,000-10,000 Kyat per day.

In hospital OPDs, the doctor records the drugs to be prescribed in the patient booklet, which is kept by the patient. An OPD patient register is kept by a nurse who assists the doctor. The patient then goes to get his/her medicines from the OPD dispensary, where a dispensing register is kept, from which consumption is estimated for re-ordering. In RHC/sub-RHCs, the prescriber keeps the OPD register and may also dispense. In general the OPD patient registers were well kept and included information on diagnosis and treatment. On average each doctor saw about 30 patients per day in the hospitals visited. In the RHCs and sub-RHCs visited the average number of patients seen per day was 5-10.

Inpatient records consist of one sheet of paper with history, examination and diagnosis recorded and with any lab tests etc. attached. In most hospitals, there was no individual patient dispensing record sheet, only a sheet hand-drawn by the nurses recording patient name with a tick against the name according to what medicines must be dispensed. Some staff said that the nurses were too overworked to keep separate patients medicines dispensing sheets. However, in one hospital with the greatest number of inpatients per nurse (16 patients as compared to 10 inpatients per nurse), individual medicines dispensing sheets were kept, and they felt it was much less time consuming than a sheet with all patients' names and ticks against which drug was needed drawn up by hand for every dispensing round. Bed occupancy was about 70-75% in the tertiary hospitals, but only 20-40% in the township hospital visited.

Traditional medicines (TRM)

Neither the CMSD nor any of the conventional public health care facilities supply any traditional medicines. Traditional medicines services are managed by the Department of Traditional Medicines which oversees separate health facilities and quality control. There are two 100-bedded, five 50-bedded and ten 16-bedded hospitals and 244 health clinics (OPD only) and about 1500 staff are employed, 75% of them traditional practitioners. By contrast the conventional health care system operates more than 1000 hospitals, 6000 rural health centres (RHCs) and sub-centres (sub-RHCs), and employs over 20,000 doctors. The majority of traditional medicine use appears to be by self-medication in pharmacies (see section 4.11).

TRM clinics are at district and township level and each one sees about 2000 patients per month. Every township also runs 3-4 mobile clinics per month these being run by both public and private practitioners and seeing 200-700 patients in one day. Clinics at township level have 3 TRM practitioners, 16-bedded hospitals have 5 TRM practitioners, 50-bedded hospitals have 14 TRM practitioners and 100-bedded hospitals have 56 TRM practitioners. "Allopathic" nurses also work in the TRM hospitals. All TRM practitioners are generalists, none are specialists, and all practice the prescription and dispensing of herbal medicines, hot fermentation, massage, and hot oil application. No injections are given.

4.9. Insurance

There is no health insurance for the majority of the population.

4.10. Drug Manufacturing

The Myanmar Pharmaceutical Factory (MPF) is the government-owned manufacturing company and it used to supply about 70% of essential medicines. However, MOH mentioned that it was only manufacturing some of the medicines on the EML and not many of the medicines that prescribers actually used. CMSD commented that the MPF was not able to supply in a timely way the quantities ordered of medicines that they do manufacture. Some orders from previous years were only just arriving. It was mentioned that there had recently been a meeting between the MOH and the Ministry of Industry in charge of the MPF about modernizing the MPF and building up its capacity so that it could manufacture the medicines that prescribers used in the quantities needed in a timely way. This apparently would mean quite some investment in the MPF infrastructure. There are very few private manufacturers in Myanmar. The Department of Traditional Medicine operates two factories for traditional medicine.

4.11. Drug management in the private sector

Three private pharmacies were visited in two areas – Pyin Oo Lwin town and Nay Pyi Daw. One pharmacy in Pyin Oo Lwin was near to the hospital and one in the town centre. The two pharmacies in Pyin Oo Lwin tended to be open 12 hours a day, stock between 1000 and 2000 items and sell medicines to about 100-200 customers per day. The Nay Pyi Daw pharmacy was open 11 hours per day, stocked about 500 items and sold medicines to about 40-45 customers per day.

In Pyin Oo Lwin it was mentioned that there were about 20 private pharmacies serving about 25-30 private GPs, none of whom was a traditional practitioner. About half the customers had a prescription from a private GP but all of the customers buying traditional medicines did so through self-medication and none of the pharmacists knew of any private traditional practitioner that wrote prescriptions. In the Nay Pyi Daw pharmacy, about one-third of all patients had a prescription.

The pharmacy owners in Pyin Oo Lwin mentioned that they procured from 30-100 dealers, and that daily sales were 3-10 Lakh, and that they made about 5% profit from their sales, which had decreased by half since the “free medicines scheme” had started in public health facilities. Sales representatives generally visit about once per month and bring samples and collect payment. However, one pharmacy owner in Pyin Oo Lwin mentioned that he had to travel monthly to Mandalay to pay the wholesalers in person and in cash. The Nay Pyi Daw pharmacy owner mentioned that procurement was done from about 20 suppliers and that approximate daily sales were 2-3 Lakh.

One pharmacy owner mentioned that the last time he had received an inspection visit from the FDA Supervisory Committee was in January 2014 when some unregistered medicines were found and confiscated. He was told not to stock such medicines again. Apparently he was unaware that the medicines were not registered. As mentioned earlier, fake drug registration documents are in circulation.

Another pharmacy owner in Pyin Oo Lwin mentioned that the general hospital medical superintendent provides a lecture on various topics 6-monthly and that about 30 pharmacists attend. Topics have included oral contraceptives, storage, combination products, etc.

Traditional Medicine

In the Pyin Oo Lwin pharmacies, of the 1000-2000 or so items stocked about 200-300 were traditional medicine products and of the 100-200 customers per day, about 25% would buy traditional medicine products. All traditional medicine products were sold without prescription to customers self-medicating. None of the Pyin Ool Lwin pharmacy staff knew of private TRM practitioners. Traditional medicines were purchased from less than 10 dealers (as compared to allopathic medicines purchased from 30-100 dealers). In the Nay Pyi Daw pharmacy, about 80% of the customers purchased traditional medicines, mostly through self-medication.

4.12. Summary status including progress, changes and problems in drug supply since the last situational analysis

Since 2011 the drug supply has dramatically changed from a centrally controlled "push" system to a decentralized "pull" system and government medicines expenditure has increased from less than 0.2 USD/person/year to about 3 USD/person/year. This has resulted in greatly improved drug availability and increased patient attendance. Availability of key essential drugs was 75-80% in hospitals and 59% in RHCs and sub-RHCs. The reason for non-availability was generally non-use and therefore non-purchase – which accounted for lower apparent availability at RHCs and sub-RHCs simply because they did not treat non-communicable diseases.

Unfortunately, the infrastructure to manage an efficient decentralized procurement system is lacking, with a lack of pharmacists in regional/state health directorates and a lack of capacity to manage technical specifications of tenders, undertake quantification, etc. Furthermore, there are now no economies of scale, since all hospitals with more than 200 beds and all states and regions are purchasing 6-monthly as opposed to central annual procurement. There appears to have been no discussion about which functions may be centralized (e.g. price negotiation, selection of pre-qualified suppliers) and which functions may be decentralized (quantification, ordering, purchase) so as to achieve both economies of scale and an efficient pull system.

Since the decentralized system started, emergency orders are still being processed by the CMSD, although it is unclear what their future role will be in procurement and distribution. Since the CMSD has the greatest capacity with regard to procurement, quantification, stock management and distribution, it would be a shame if their skills were not fully utilized. Unfortunately, an electronic drug management information system has not been established and insufficient pharmacists are involved in the decentralised procurement and stock management system.

4.13. Medicines Supply: Recommendations

- Establish harmonised, functional, electronic drug management information system, to monitor consumption, stock-out, expiry which is necessary to improve quantification:
    - start centrally/regionally & then extend to district/township level,
    - employ a data-entry staff for this purpose at each hospital & district/township.

- Employ at least one pharmacist in stock management at regional health offices and district/township hospitals.

- Train staff in monitoring medicine consumption and quantification.

- Develop policies to better manage drugs and contain costs in the new decentralised procurement system:
    - Review and clarify the roles of the public (MPF and CMSD) and private sectors in procurement and supply. This would include consideration of what functions should be done centrally (e.g. price negotiation, and prequalification of suppliers and products) and what functions locally by hospitals, regions and states. This may need discussion between the MOH, Ministry of Industry and Ministry of Trade/Commerce and could be done by the Additional Health Committee, chaired by the Vice President.
    - Review the drug management system with regard to the push and pull systems, double book-keeping system (for CMSD and local procurement) and in-patient ward management of drugs.

5. MEDICINE SELECTION

5.1. National Essential Medicines List (EML)

From review of the national EML:

- Responsible government department or agency: Essential Drug Program, Medical Care Division, Department of Health
- Date of publication of latest EML: 2010; revision in process during 2014
- Previous publication dates: 2001; 1998; 1987; 1984; 1979
- Number of active pharmaceutical ingredients (APIs) in the 2010 EML: 341
- Number of formulations for all APIs in the 2010 EML: > 400
- Number of products (incl. all brand names and formulations) registered on the market: > 17,000
- Categories by level of use in national EML:
    - Essential and complementary,
    - Tertiary referral level and other levels
- Number of persons involved in drafting the latest EML 2014, which is in process:
    - Core team: Deputy Director Generals of the Divisions of Medical Care, Public HEALTH, Disease Control, CMSD, FDA, one physician, one surgeon, and the Chief (Deputy Director) of the Essential Drug Program (secretary)
    - Experts: Pharmacologists from Universities of Medicines and allied Universities in Myanmar and a WHO consultant from the faculty of medicines in Chulalongkorn University in Thailand.
- Specialties represented (including general practice):
    - All specialties including general practitioners were represented.
- Geographic representation of experts: Unknown
- Consistency with national STGs? There are no national STGs for most common conditions.

5.2. Other Medicine Lists

Central procurement

The CMSD has a list of 114 items that it procures, 9% of which are non-EML. Many of the medicines are procured from the Myanmar Pharmaceutical Factory. Selection of non-EML medicines is done on the basis of demand by hospital superintendents and State/Regional Health Directors.

Regions and States

Each region and state is now undertaking local procurement. Of the township hospitals, RHCs and sub-RHCs visited, 10-23% of medicines did not belong to the EML. Selection of non-EML medicines is done on the basis of demand by hospital doctors and superintendents, with the ultimate decision being taken by the State/Regional Health Directors.

Tertiary Referral Hospitals

Each tertiary referral hospital with more than 200 beds is now undertaking local procurement. Of the three tertiary referral hospitals visited, 21-39% of medicines did not belong to the EML. Selection of non-EML medicines is done on the basis of demand by heads of specialist departments in conjunction with the medical superintendents.

5.3. Development / updating of national EML

The situation with regard to development and updating of the national EML has not changed since 2011 since the 2010 national EML has not yet been updated, though an update is in process. A national workshop was held in 2014 and a revised EML drafted, with categorization by prescriber level, but it has yet to be approved by the MOH. Briefly, the 2010 national EML is the 6th edition and has only has 341 active pharmaceutical ingredients, subdivided by use at tertiary level and other levels. It includes essential and complementary medicines. Unlike previous lists it is not categorised by prescriber type or level of facility apart from tertiary hospital and other levels. A core committee of eight MOH officers oversaw the drafting of the EML but it is not clear how many other experts were involved in the development process. There is a lack of transparency in the process, as the selection criteria used, sources of evidence, process for addition and deletions, etc. are unknown.

In 2014 a national workshop, attended by 30 persons, including pharmacologists and representatives of all the major specialties, was held earlier in the year to update the national EML, supported by WHO, and a new draft made, with categorisation of medicines by level of prescriber. The draft has yet to be approved. The inclusiveness of the process is uncertain since some of the workshop participants recommended that a further national workshop be held to finalize the revised EML.

5.4. Implementation of EML

National policy dictates that the majority of medicines used in the public sector should belong to the EML. Central procurement still follows this policy but, with local purchase, the hospitals are using more non-EML medicines although the majority of medicines used still belonged to the EML. In the township hospitals, RHCs and sub-RHCs visited, 10-23% of medicines did not belong to the EML and in the tertiary referral hospitals visited 16-30% of medicines did not belong to the EML.

No copies of the national EML were seen in the health facilities although everyone knew of it. In the recent survey by SCMS/MSH (Tolliver 2014), it was mentioned that the EML did not seem to be the driving factor with regard to purchase. While medical students are taught about the EML, they are now beginning to see many other non-EML drugs being used in their clinical studies.

The only past information found on EML implementation came from the 2011 situational analysis where it was found that the % of prescribed drugs belonging to the EML was 62% in public referral hospitals, 94-98% in public township hospitals, RHCs and sub-RHCs, and 59% in private pharmacies (Holloway 2011). At that time, availability of essential medicines was very low. Prescription review during the 2014 situational analysis (section 6), when drug availability was good, shows that the percentage of prescribed medicines belonging to the EML was 75% in tertiary hospitals, 84-89% in township hospitals, RHCs and sub-RHCs, and 54% in private pharmacies. Thus it would seem that compliance with the EML has slightly increased in tertiary hospitals but slightly decreased in the lower level facilities although compliance still remains high. EML compliance in private pharmacies was similarly low in 2011 and 2014.

ABC analyses of 2013 procurement data (section 4) shows that EML medicines constituted 90% of the drugs purchased by the CMSD (mostly supplying lower level facilities) and 70-84% of the drugs purchased by tertiary hospitals. It also showed that two tertiary referral hospitals also purchased small amounts of monotherapy artemether (tablets and injectables) in 2013 and monotherapy is on the 2010 EML – so national policy in the public sector has allowed the selection and use of artemether monotherapy despite international and national regulatory efforts for many years to stop the use of monotherapy artemether for fear of encourage resistance.

Table 5.4.1: EML drug availability and use from observation and record review in the health facility surveys

Public Referral Hospitals	1	2	3		Average
% key EML drugs available*	60%	90%	91%		80%
% items that are non-EML	58/218=27%	47/223=21%	114/293=39%		
% prescribed drugs belonging to the EML**	72.3%	71.1%	81.2%		73.4%
EML available in pharmacy? Yes/No	No	No	No		No
Public District Hospitals	1	2			
% key EML drugs available*	58%	92%			75%
% items that are non-EML	?	55/275=20%			
% prescribed drugs belonging to the EML**	88.7%	90.1%			89.4%
EML available in pharmacy? Yes/No	No	No			No
Public primary health care centre	RHC 1	sub-RHC 1	RHC 2	sub-RHC 2	
% key EML drugs available*	61%	49%	75%	50%	59%
% items that are non-EML	38/167=23%	7/71=10%	10/117=9%	14/94=15%	
% prescribed drugs belonging to the EML**	88.0%	86.3%	78.1%	85.5%	84.5%
EML available in pharmacy? Yes/No	No	No	No	No	No

* Belonging to the national EML or the provincial / hospital formulary in decentralized systems – please see the same indicator recorded in the section on drug supply under drug availability

** From prescription audit done during the health facility surveys

5.5. Summary status including progress, changes and problems in drug selection since last situational analysis

The national EML 2010 contains 341 drugs divided into those recommended for use at tertiary level and those for use at other levels and also including essential and complementary categories for both groups. It is currently being updated and a national workshop, supported by WHO, was held to revise it, but it has not yet been approved by MOH. As previously recommended, the new EML will have medicines categorized by level of user. However, the inclusiveness and transparency of the process are not clear since some workshop participants requested a further national workshop to finalize the EML.

Government policy is that that EML drugs should be used in the public sector and, even following decentralization and local purchase, procurement of EML drugs was over 90% in the CMSD (mostly supplying lower level facilities) and 70-84% in tertiary hospitals. Previous recommendations to form a Drug and Therapeutic Committee in every hospital to provide guidance on what non-EML medicines maybe purchased and to monitor compliance have not been followed. This may become increasingly important as hospitals get used to undertaking local purchase and as more and more products become available in Myanmar.

5.6. Drug Selection: Recommendations

- Revise the Essential Medicines List (EML) (in process):
  - include drugs for all levels of care;
  - classify each drug according to therapeutic class and level of care (both facility level and prescriber level);
  - have wide representation of specialists, pharmacologists, generalists & pharmacists, and transparent process to improve acceptance.

- Implement the revised EML:
  - Consider policy to ensure that most local procurement (e.g. 80% at tertiary level and 90% at township level) consists of EML drugs;
  - Ensure all providers are sensitized/trained on the EML;
  - Monitor compliance to the EML (through consumption analysis and prescription survey).

- Establish a transparent system to review all requests for non-EML drugs:
  - Drug and Therapeutic Committees in each district and tertiary hospital could consider such requests.

MEDICINE USE

6.1. Responsible Agents/Departments

From discussion with senior MOH officials

Function/ Organisation	MOH	Other Agency	Name of Agency/MOH Department
Monitoring medicines use in hospitals	?		Medical Superintendent and Head of each clinical department but very little routine monitoring done.*
Monitoring medicines use in Primary care	?		State/Regional Health Director, District and Township Medical Officers but very little routine monitoring done.*
Development of national STGs	√	√	Essential Drug Program for PHC STGs; Myanmar Academy of Medical Science developing STGs for secondary care; Medical Care Division & l Disease Control Programs for other STGs
Development of national formulary	?		No national formulary manual
Drug Information Centre	?		No national drug information centre
Provision of independent drug information	√		Department of FDA and Medical Care Division, MOH
Monitoring Hospital DTCs	√		Medical Care Division, MOH, responsible but there are no hospital DTCs, only procurement committees
Monitoring Hospital quality of care	√		Medical Care Division, MOH
Monitoring DTCs in provinces/districts	√		Medical Care Division, MOH, responsible but there are no hospital DTCs, only procurement committees
Undergraduate education for health professionals	√		Department of Medical Science, MOH
Continuing medical education for health professionals	√		Department of Medical Science for postgraduate courses. MOH for refresher courses; Myanmar Medical Association for CME
Public education on medicines use	√		Division of Public Health and Division of Health Education under the Department of Health
Implementing generic policies	?		Generic policies are not yet implemented, although there is a plan to put it into the National Medicines Policy.

*The Project Manager of Myanmar Essential Medicines Project and Officials from Department of Health have conducted some monitoring of medicine use in hospitals and primary care level.

6.2. Past prescription surveys

Only one previous prescription survey done in the last 10 years was identified – the one done during the situational analysis of 2011, results shown below.

Table 6.2.1: Results of situational analysis prescription survey done in 2011

Indicators	Holloway KA. Pharmaceuticals in Health Care Delivery: Situational analysis. WHO/SEARO, 2011.
Year of survey	2011
Facility type	2 referral hospitals, 3 township hospitals, 5 RHCs and sub-RHCs, 2 private pharmacies
Public / private	Ten public facilities and 2 private pharmacies
Average number of drugs per patient	2.7-2.8 hospitals; 2.1 RHC/sub-RHC; 2.3 private pharmacies
% patients prescribed antibiotics	27-56% hospitals; 31% RHC/sub-RHC; 9% private pharmacies
% patients prescribed injections	25-32% hospitals; 5% RHC/sub-RHC; 1% private pharmacies
% drugs prescribed by generic name	4% tertiary hospitals; 51% township hospital; 75% RHC/sub-RHC; 9% private pharmacies
% prescribed drugs belonging to the EML	62% tertiary hospitals; 94-98% township hospital/RHC/sub-RHC; 59% private pharmacies
% URTI patients prescribed antibiotics	100% township hospitals; 72% RHC/sub-RHC
Average cost per prescription (Kya)	5665 Kyat tertiary hospitals; 1241 Kyat township hospitals; 4364 Kyat pharmacies.

6.3. Current prescribing practices

A prescription survey in public facilities was done reviewing 30 prescriptions from general medical officers in hospitals and the paramedical prescribers in RHCs and sub-RHCs on the day of the visit to each facility. Care was taken to select only primary care type cases in the hospitals. Data for general prescribing indicators was collected prospectively from the OPD patient registers in most facilities. Prescriptions are recorded in booklets kept by the patients and no patient records or prescriptions are kept in the OPD pharmacy so data could not be collected retrospectively from there. In addition, 30 prescriptions for upper respiratory tract infection were reviewed from the OPD patient registers (which were generally maintained by nurses assisting the doctors in hospitals and by the paramedical prescribers themselves in RHC/sub-RHCs) and where both diagnosis and treatment were recorded. In the case of North Okkalapa General Hospital, prescribing data was collected from actual patient booklets as patients came to the OPD pharmacy for the medicines to be dispensed. For Township hospitals, RHCs and sub-RHCs, prescribing practices were analysed for both OPD and outreach/mobile clinics. In private pharmacies, data was collected from 30 patients as they came to the pharmacy to purchase medicines. There were no records kept in the pharmacy so the only means of collecting data was from patients. The cost per prescription was based on what the patients paid, not on what was prescribed, which may have been more than what was bought.

The results of the prescription survey done during this situational analysis are shown below.

Table 6.3.2: Results of prescription audit from health facility survey

Public referral hospitals Doctor prescribing	1	2	3		Average
Average number of drugs per patient	3.4	3.2	3.3		3.3
% patients prescribed antibiotics	14.3	43.5	45.2		34.3%
% patients prescribed injections	14.3	40.0	45.2		33.2%
% patients prescribed vitamins	28.6	30.0	58.1		38.9%
% drugs prescribed by generic name	47.9	58.8	54.5		53.7%
% prescribed drugs belonging to the EML	72.3	71.1	81.2		74.0%
% URTI patients prescribed antibiotics	-	80.0	66.7		73.4%
Average cost per prescription	5996				5996
Public Township hospitals and outreach clinics run by the hospitals	Hospital 1	Outreach from hosp 1	Hospital 2	Outreach from hosp 2	Average
Average number of drugs per patient	3.4	3.1	2.8	3.4	3.2
% patients prescribed antibiotics	29.0	33.3	70.0	43.3	43.9%
% patients prescribed injections	0.0	60.0	40.0	10.0	27.5%
% patients prescribed vitamins	77.4	53.3	23.3	73.3	56.8%
% drugs prescribed by generic name	64.1	66.7	66.3	72.3	67.4%
% prescribed drugs belonging to the EML	84.9	92.4	83.1	97.0	89.4%
% URTI patients prescribed antibiotics	83.9	90.0	83.3	-	85.7%
Rural Health Centres (RHCs) and outreach clinics run by the RHCs Health Assistants prescribing (3 years training)	RHC 1	Outreach 1	RHC 2	Outreach 2	Average
Average number of drugs per patient	2.6	2.7	1.9	1.5	2.2
% patients prescribed antibiotics	50.0	50.0	66.7	50.0	54.2%
% patients prescribed injections	0.0	33.3	0.0	6.7	10.0%
% patients prescribed vitamins	53.3	46.7	6.7	16.7	30.9%
% drugs prescribed by generic name	75.6	72.5	79.3	76.1	75.9%
% prescribed drugs belonging to the EML	92.3	83.7	93.1	63.1	83.1%
% URTI patients prescribed antibiotics	80.0	86.7	100.0	-	88.9%
Sub-Rural Health Centres (sub-RHCs) Midwives prescribing (1.5-2 year training)	sub-RHC 1	sub-RHC 2	Outreach from sub-RHC 2		Average
Average number of drugs per patient	3.2	2.2	1.3		2.2
% patients prescribed antibiotics	70.0	63.3	23.3		52.2
% patients prescribed injections	13.3	0.0	0.0		4.4
% patients prescribed vitamins	76.7	40.0	46.7		54.5
% drugs prescribed by generic name	64.2	83.3	57.5		68.3
% prescribed drugs belonging to the EML	86.3	93.4	77.5		85.7
% URTI patients prescribed antibiotics	96.7	90.0	100.0		95.6

Table 6.3.2 on prescribing continued

Private-for-profit pharmacies	Pyin Oo Lwin 1	Pyin Oo Lwin 2	Nay Pyi Taw		Average
Average number of drugs per patient	1.9	2.3	2.3		2.2
% patients prescribed antibiotics	31.0	13.4	6.3		16.9
% patients prescribed injections	6.9	8.7	9.4		8.3
% patients prescribed vitamins	11.1	26.1	31.3		22.8
% drugs prescribed by generic name	20.7	26.4	29.7		25.6
% prescribed drugs belonging to the EML	55.6	45.3	60.8		53.9
% URTI patients prescribed antibiotics	-	-	-		-
Average cost per prescription (Kyat)	3983	4469	7088		5180

The prescribing survey shows that more medicines are being prescribed in 2014 as compared to 2011. Thus, the average number of medicines per patient, and the number of patients receiving antibiotics, injections and vitamins is greater. This is not surprising since the availability of medicines is much greater in 2014 as compared to 2014. As before, the higher the level of facility, the greater the number of medicines are prescribed per patient and the greater the number of patients prescribed injections, and this is expected since more complex cases are seen at higher level facilities. Tertiary hospitals also have lower prescribing of EML medicines and prescribing by generic name than lower level facilities. Nevertheless, compliance with the EML was high in all public facilities.

Antibiotic use for upper respiratory tract infection was extremely high in all health facilities and was similar in 2011. In some outreach clinics run by the township hospitals, RHCs and sub-RHCs, the prescribing in the outreach clinic was quite different from that in the OPD of the facility from which the outreach clinic was sent. In particular, in some outreach clinics, there was higher use of injections than in the OPD and the appropriateness of this should be investigated.

Prescribing in township hospitals and above was by medical doctors, in RHCs by Health Assistants of 3 years training and in sub-RHCs by midwives of 1.5-2 years training. On discussion with OPD doctors, most general medical officers in township and tertiary hospitals saw about 30 patients per doctor per day. In some of the RHCs and sub-RHCs visited, health assistants and midwives saw similar numbers of patients per day while in others, they were seeing only 10-20 patients per day. In 2011, patient attendance was much less, with doctors seeing only about 10 patients per day on average. Thus doctors are not over-burdened and can give sufficient consultation time to patients. Most prescribers did not feel that irrational use of medicines was a problem, although senior staff in the Academy of Medical Sciences and pharmacologists from University of Medicines I, felt that it was a problem.

Most public sector doctors also practice privately in the evenings. Prescribing of EML medicines and prescribing by generic name was much lower in private pharmacies which serve some private practitioners although other private practitioners undertake their own dispensing. The average amount paid by patients in the private pharmacy in the OPD of N. Oakkalapa tertiary hospital in Yangon was similar to the amount paid in private pharmacies in the Mandalay and Nay Pyi Daw areas and only slightly higher than that paid in 2011.

6.4. Dispensing Practices

6.4.1. Health Facility Outpatients

Dispensing in the OPD pharmacies of public facilities was generally done by compounders of one year's training or paramedical staff. In some large tertiary hospitals, one dispenser may have to dispense medicines to more than 100 patients, but in most facilities it was much less than this. Thus many dispensers had sufficient time to spend with patients and educate them on how to take their medicines. Even so, in the few facilities where dispensing could be observed, the patient-dispenser interaction time was often less than one minute and there was no labelling apart from writing the number of tablets and the frequency per day on the strip packing.

6.4.2. Health Facility Inpatients (wards)

The record keeping for actual dispensing of medicines to inpatients was poor and in some circumstances dangerous. There were no individual patient records for administration of medicines. Rather, for each dosing period, the nurses wrote out a summary dosing chart for all patients which consisted of list of patient names down the left-hand-side of the page and with columns for different drugs, the names being listed across the top of the page. The nurse ticked in the relevant column and row to indicate which medicine had to be administered to which patient. For each dispensing round such a sheet had to be drawn up, getting the information from the patient records. This system was quite time consuming for the nurses to manage and is also potentially dangerous since a nurse could be distracted by an emergency in the middle of a dispensing round and actually forget whether a patient had been given a medicine or not. Since there is no written indication on the patient notes of whether each dose of each medicine was actually given, some forms of inpatient drug utilization review cannot be done.

Only in one hospital, Pyin Oo Lin, was an individual inpatient drug dispensing sheet used. In this hospital, each nurse had to look after about 16 patients – much more than in the other hospitals visited - yet the nurses felt the system of individual inpatient drug dispensing sheets was very time efficient.

6.4.3. Private pharmacies

Dispensing in private pharmacies was often done by unqualified staff, supervised by a shop-owner who had some kind of graduate qualification but not one in pharmacy. In one pharmacy the owner was a lawyer and his wife was a nurse. Comparison of the average numbers of customers per day and the number of shop assistants, revealed that dispensers were dispensing to less than 30 customers per day. Nevertheless, patient-dispenser interaction time was often less than one minute and there was no labelling. Some medicines were stored sub-optimal conditions. About half the customers had prescriptions but some of these were informal pieces of paper.

6.5. Policies to promote rational use of medicines

6.5.1. Monitoring and supervision of prescribing/dispensing by supervisors

No monitoring, prescription audit or drug utilization review has been or is being done on a regular basis. The pharmacology departments in various medical colleges and the pharmacy university do not appear to have conducted any surveys of medicines use. The pharmacology department of University of Medicine I stated that they are planning to do such studies in the future and that they were just organizing a survey by medical students of pharmacy shops.

6.5.2. Standard Treatment Guidelines (STGs)

There are national Standard Treatment Guidelines (MOH 2006), aimed at primary care, published for 4 different categories of health workers - medical officers, Health Assistants, Midwives and Voluntary Health Workers. A newer STG for Basic Health Staff (BHS) was produced in 2013 and distributed to all BHS with financial aid mostly from Government and from WHO. Though many prescribers knew of these guidelines, few appeared to be using them. The Myanmar Academy of Medical Sciences (MAMS) together with the Myanmar Medical Association has developed and published Standard Treatment Guidelines on Paediatrics and is in the process of developing guidelines for obstetrics and gynaecology for use in hospitals. Development of clinical guidelines for medicine and surgery are planned. However, it is not clear what experts/specialists have been involved in the process (i.e. how inclusive the process has been) and whether the MOH will accept these treatment guidelines.

6.5.3. National Formulary

The Myanmar Medical Association and the Myanmar Pharmaceutical Association have produced a Myanmar Pharmaceutical Index in 2010 which contains information on most but not all the drugs registered. The medicines are listed by generic name with the various brand names listed underneath. Unfortunately there is no brand name index so the book appears to be used mainly to see what different brands there are for different active pharmaceutical ingredients (APIs) rather than to see what the API is in any branded product. The book is funded by the companies whose adverts appear in the book. Few doctors or facilities had this book.

6.5.4. Drug information Centre

There is no national drug information centre.

6.5.5. Independent drug information

There are few sources of independent information. Few people were using internet. Some teaching hospitals receive journals. It was stated by MAMS that most doctors get their information from medical representatives.

6.5.6. Drug and Therapeutics Committees

There is no national DTC and there are no Drug and Therapeutic Committees in any of the hospitals or district/township health authorities, nor did the hospitals carry out many of the functions that a DTC may be expected to undertake such as managing a formulary system, prescription audit, monitoring of adverse drug reactions or coordinating continuing medical education on prescribing. In hospitals of more than 200 beds, where they are able to undertake local purchase, there are purchase committees, which decide which drugs to purchase, but which do not undertake any other functions.

6.5.7. Undergraduate education on medicines use

Medicine

Pharmacology teaching consists of 187 hours during the 3rd year of undergraduate medical school and consists of lectures, tutorials and some practical sessions. There is no specific teaching on the national EML or on any national standard treatment guidelines. Unfortunately there is no pharmacology tuition during the 4th and 5th years of undergraduate medical education so whatever is learnt in the 3rd year may be undermined by later clinical studies and work. It is unclear how much focus is given to prescribing skills. There is very little interaction between the university hospitals and the medical school pharmacology department. The curricula must be approved by the Medical Council.

Pharmacy

The pharmacy university has one branch in Yangon and one in Mandalay and produces about 150 pharmacists per year. Unfortunately, only about 15% of all graduates find any job in the public sector, there rest finding work in the private sector.

Pharmacy undergraduate education consists of a 2-year diploma course and a 4-year bachelor course and both courses include some pharmacology. It is not clear how much focus is given to practical skills in monitoring medicines consumption, supply chain management, procurement, etc., although all BPharm students must do a 2-month clinical posting in public hospitals during their final year. There is a plan to introduce a one-year internment program for BPharm students.

Paramedics

Health Assistants, midwives and other cadres of paramedical worker are taught at Magway University. The MOH approves the curricula and has produced standard treatment guidelines for basic primary care aimed at this cadre.

Traditional Medicine

There is one university in Mandalay that runs a Bachelor course on traditional medicine. The course is four years and more than 2000 practitioners have been trained. There is no specialization and there are no post-graduate courses.

6.5.8. Continuing Medical Education on medicines use

Continuing medical education (CME) is organized in the same way as in 2011. Thus, the heads of individual units in teaching hospitals organize seminars and teaching ward rounds for in-service staff. The MOH vertical disease control programs run refresher training for district level staff from time to time. Supervisory visits are made by township staff to RHCs and from RHCs to sub-centers monthly. However, there is very little focus on prescribing and none has utilized prescription audit and feedback. Outside of teaching hospitals, CME for doctors is adhoc and not mandatory. There is still no postgraduate program in clinical pharmacology although one is planned. All postgraduate programs are only available through competitive examination after 2 years of government service. The University of Pharmacy started a new clinical pharmacy program in 2010 and the curriculum includes pharmaceutics, pharmacy business and pharmacology. All medical specialties have specialist societies, which are part of the Myanmar Medical Association, but their role in post graduate education is unclear. Thus, as in 2011, since there is no clinical pharmacology specialty, many practical skills such as those needed for monitoring ADRs, drug utilization review, etc. are not taught.

In the private sector, many doctors are not undertaking any form of CME. The Myanmar Medical Association (MMA), which is the only body totally independent of government, continues to run a CME course for private practitioners. There are four modules which general practitioners should complete over a period of four years, after which they get a completion certificate. The CME consists of lectures and practical sessions conducted mostly at weekends. While there is provision to get the training materials and do the modules long distance, they cannot get a completion certificate so few do it. Altogether 1700 general practitioners have completed all four modules and over 4000 have completed some modules. It is not clear how much attention is given to general prescribing skills in these courses. The MMA is currently trying to get accreditation for this private GP CME from the Myanmar Medical Council (MMC).

6.5.9. Public Education on the safe and prudent use of medicines

There have been no public education campaigns to improve the use of medicines. In the sub-centres and RHCs there are staff who undertake public education on maternal child health, treatment of childhood illness, vaccination and so on. However, the focus of their messages has generally not been on medicines use. Many health workers felt that patient demand was a problem and that public education was needed, particularly since so many patients self-medicate. Relevant messages could include “don’t take antibiotics without seeing a health worker first” or “medicines are not needed for simple coughs and colds” or “ask your doctor whether your child really needs more than 2 medicines”.

6.5.10. Generic Policies

There is no generic prescribing policy in the public sector although the majority of medicines are prescribed by generic name at township level and below. Generic policies are being considered for inclusion in the national medicine policy, which is currently being formulated.

6.6. Summary status including progress / changes / problems in medicines use since last situational analysis

Consumption of medicines has greatly increased since 2011, in line with increased government expenditure on medicines. The average number of drugs prescribed per patient in public hospitals was 2.7-2.8 in 2011 but 3.2-3.3 in 2014. Despite the change from central to local purchase, compliance with the EML was high, the percentage of prescribed drugs belonging to the EML being 75-89% in the public sector as compared to 54% in the private sector. The percentage of drugs prescribed by generic name was 54-73% in the public sector and 26% in the private sector. Irrational use of medicines remains a very serious problem. The percentage of upper respiratory tract infection cases treated with antibiotics was very high in all facility types, being 73-92%. Vitamin use was also high, with 39-57% of patients being treated with vitamins in the public sector and 23% in private pharmacies.

There is little monitoring of medicines use and little implementation of policies to promote rational use of medicines, as was found in 2011. There are national standard treatment guidelines for primary care mainly aimed at paramedical workers but they appear to be little used by doctors working in primary care. There are guidelines for secondary care under development by the Myanmar Academy of Medical Science in collaboration with the Myanmar Medical Association but it is uncertain that MOH would adopt these as national guidelines. The discipline of clinical pharmacology is still not developed but the University of Pharmacy has established a post-graduate course on clinical pharmacy. Continuing medical education is adhoc for most practitioners, some refresher training being provided by MOH for public sector prescribers and some by the Myanmar Medical Association for private GPs but there appears to be little focus on prescribing. Hospitals only have procurement committees but not drug and therapeutic committees (DTCs), and public education campaigns on the safe and prudent use of medicines have not been conducted.

6.7. Medicines use: Recommendations

- Monitor medicines use:
  - Include prescription audit using diagnosis, which would require that all out-patient registers have diagnosis and drugs recorded;
  - Identify specific inappropriate practices that you want to change (e.g. overuse of antibiotics in upper respiratory tract infection) in order to target interventions to these practices;
  - Should be done by all teaching hospitals and State/Regional health offices.

- Develop National Standard Treatment Guidelines (STGs):
  - Cover secondary as well as basic primary care;
  - Incorporate the activities of the Myanmar Academy of Medical Sciences to develop STGs;
  - Disseminate to every doctor and incorporate into continuing medical education (CME) and undergraduate education.

- Establish Hospital Drug and Therapeutic Committees:
  - Require them to monitor drug use, encourage CME, and report annually on activities to MOH;
  - Pharmacists can act as DTC secretaries and implement DTC decisions.

- Review hospital in-patient dispensing procedures:
  - Develop a printed form in which the nurse must sign for each dose of each medicine given, as used in Pyin Oo Lwin general hospital.

- Undertake public education on the prudent and safe use of medicines:
  - Undertake public education campaigns which could be spread through Community Health Workers and the media;
  - Include core pharmaceutical messages e.g. *Antibiotics are not needed for simple coughs & colds.*

- Strengthen continuing medical education (CME) with regard to medicines use:
  - Myanmar Medication Association and Myanmar Medical Council could develop a credit system for CME;
  - Incorporate prescription audit and feedback and ethics into CME;
  - Develop the disciplines of clinical pharmacology and clinical pharmacy.

- Consider establishing a national drug information centre:
  - To provide prescribers with independent information.

7. MEDICINE REGULATION

7.1. Responsible Agents/Departments

Regulatory function	DRA	Other Agency	DRA/MOH department/Name of Agency
Drug Schedules	√		Department of Food and Drug Administration (FDA), Myanmar
Licensing & Inspection of drug outlets	√	√	Food and Drug Supervisory Committees at regional, district, township levels for regular control and inspection; central FDA licenses pharmacies that sell controlled medicines
Drug registration	√		FDA
Pharmacovigilance	√		FDA is responsible but has no unit working on this.
Drug quality testing	√		FDA
Drug promotion	√		FDA does pre-approval of adverts for OTC medicines
Drug pricing		√	Myanmar Pharmaceutical and Medical Equipment Entrepreneur Association in association with Ministry of Commerce, especially for imported drugs
Health professional licensing/accreditation		√	Myanmar Medical/Pharmacy/Nursing Councils; Medical Care Division, MOH, for licensing of paramedical workers
Health facility/hospital licensing/accreditation		√	Medical Care Division, MOH, for licensing of hospitals

7.2. Pharmaceutical sector

- Number of products on the market:
  - About 17,000 allopathic medicines (regulated by the Department of Food and Drug Administration);
  - About 12,000 traditional medicines, all OTC, (regulated by the Department of Traditional Medicine which mentioned that some unregistered products also sold by traditional practitioners;

- Number of manufacturers:
  - 8 for allopathic medicines and main government manufacturing unit is Myanmar Pharmaceutical Factory (MPF) under the Ministry of Industry;
  - 2 government manufacturers for traditional medicines used in in government traditional medicine facilities and run by the Department of Traditional Medicine in the MOH.

- Number of wholesaler outlets/importers: 170

- Number of retailer outlets: About 10,000 for allopathic medicines, which also sell traditional medicines, there being no special shops, or licenses needed, to sell traditional medicines.

- Enforcement of regulations in 2013:
  - About 40 cases prosecuted in liaison with the Myanmar Police Force.

7.3. Current Medicines Legislation[1] (key documentation)

a) Summary of Laws/Regulations in place:

Name of Law or Regulation	Year
National Drug Law	1992
Amendment to National Drug Law to increase the penalty (in terms of fines) for contravening regulations and to change the membership of the FDA Board of Authority, which is chaired by the Minister of Health	April 2014
Notification of Ministry of Health	?

b) Coverage: *indicate with Y (Yes) or N (No)*

Area / Activity Covered?	Y/N	Document Name
Establishment & functioning of National MRA	Y	
Medicines marketing authorisation	Y	
Medicines scheduling	Y	
Licensing of medicines handling premises, personnel & practices	Y	
Licensing of prescribers	N	Myanmar Medical Council, MOH
Mandatory CME for prescriber licence renewal	N	Myanmar Medical Council, MOH
Licensing of pharmaceutical personnel	N	Pharmacists only need a degree not a license
Mandatory CME for pharmacy licence renewal	N	
Regulatory inspections/ enforcement activities	Y	Township Food and Drug Supervisory Committees
Medicines quality	Y	
Medicines packaging & labelling	Y	
Medicines promotion	Y	
Post-market surveillance/ pharmacovigilance	Y	Notification of the MOH
Collection of fees for licences	N	
Clinical trials	N	
Generic substitution	N	
TRIPS-related issues	N	
Transparency & accountability[2]	N	
Banning of unsafe medicines	N	

[1] Medicines regulation issues may be covered in more than one law and may have multiple associated regulations, so ensure that all relevant documentation is identified & obtained for review.

[2] Includes provisions for the MRA to define and publish its policies and procedures, publicly account for its decisions, conduct and actions, and follow a regulatory code of conduct.

7.4. National Regulatory Authority for medical products

- Name of National Drug Regulatory Authority: Department of Food and Drug Authority, Myanmar
- Total number of staff: 392 staff; 263 in Nay Pyi Taw and 129 in branch offices
    - Total number of technical staff: 86 (in Nay Pyi Taw, Yangon and Mandalay for the drug enforcement and quality control sections)
    - Total number of non-technical staff: 40
- Website address: Development in process
- Number of quality-control (drug testing) laboratories: 3
- Annual report of activities: Yes in Myanmar language
- Annual Budget last year: Unavailable

- Written SOPs for the following key regulatory procedures?

Key procedure	Written SOP? (Yes/No)	Details/language
Product dossier evaluation	Yes	ASEAN SOP and Myanmar checklist (English)
Registration of medicines	Checklist	English
Inspection of manufacturing premises	Checklist	Myanmar
Inspection of retail premises	Checklist	English
Sampling for Quality Control testing	SOP	English
Medical product recall or withdrawal	SOP	Done according to notification

- Position in hierarchy of government structure: Department under the Ministry of Health, Director General level.

- Decentralised capacity?
    - Number of branch offices: 14, one per State/Region;
    - Number of staff in each office: 129 in total, about 5 in most branch offices, but 30 in Yangon and 16 in Mandalay branches;
    - Functions of branch offices: Drug outlet inspection, participation in the State and Regional Food and Drug Supervisory Committees and post-market sampling;

- Functions outsourced to public health authorities: Drug outlet inspection is outsourced to the Food and Drug Supervisory Committees at district and township level. The township hospital medical superintendent is the Chairperson of the committee at township level.

- Technical committees to advise the FDA
    - Drug Advisory Committee which approves the registration of drug products.
    - Central Food and Drug Supervisory Committee which oversees all the activities of the Department of Food and Drug Administration, including the: issuing and control of licenses to all drug outlets, issuing of drug registration certificates, and issuing of GMP certificates. The Chairman of this committee is the Director General of the Department of Health, the Secretary is the chief (Director-General) of the Department of the Food and Drug Administration and members include the chief of the Division of Public Health, chairman of the City Development Committee, and representation of the departments of police, customs, general affairs and veterinary surgery.

Traditional Medicine

The department of traditional medicine regulates the sector of traditional medicines. There is a regulatory committee chaired by the DG TRM, which decides upon which products to register, and there are now about 12,000 TRM products registered. There is a laboratory which can test the quality of traditional medicine products. It is not clear whether the laboratory could test for contamination of traditional medicine products with allopathic medicines. It was mentioned that there is no licence needed to sell traditional medicines and that many TRM practitioners are dispensing unregistered products. There is no inspection of shops selling TRM products.

The DG of the Department of TRM chairs the regulatory committee, the Director of the Herbal Gardens is the secretary and members include the police, the FDA, the national health lab, the Nay Pyi Taw Council development committee and senior TRM practitioners. It is not clear what the committee does apart from registering products, particularly since TRM practitioners sell unregistered TRM products, shops do not need a licence to sell TRM products and there is no inspection of shops selling TRM products. Since the FDA inspects shops, they could cover both areas during an inspection, but it was not clear that they were doing so.

7.5. Drug Schedules

There are four drug schedules:

(1) over-the-counter (OTC) medicines,

(2) prescription-only medicines (POM), which is divided into POM category covering general non-OTC medicines and a special category covering 2nd line anti-TB drugs and anti-cancer drugs,

(3) limited controlled medicines e.g. benzodiazepines,

(4) highly controlled medicines e.g. morphine, ketamine.

The 1992 Drug Law does not specifically mention any drug schedules and in practice both OTC and prescription-only medicines may be bought in any pharmacy shop without prescription. The FDA takes administrative action and enforcement measures with regard to controlled and highly controlled medicines but cannot take any punitive action against the selling of prescription-only medicines without prescription. Controlled medicines can only be dispensed with prescription from a pharmacy with a special license issued by the central FDA in conjunction with the Narcotic Control Division of the Police under the Ministry of Home Affairs. A diploma pharmacist must be present in such pharmacies. An up-to-date OTC list was not available during the visit and personnel in private pharmacy shops were not aware of a specific OTC list. The only distinguishing feature of OTC medicines versus other medicines is that adverts are permitted for OTC medicines but not for other medicines. The FDA has distributed the OTC list to the State and Regional Offices.

7.6. Regulation and inspection of drug outlets

Issuing of licenses and regulatory inspection visits of retail pharmacies is delegated to the Food and Drug Supervisory Committees at district and township level, which are supervised by similar committees at State and Regional levels. There is a checklist for retail pharmacy inspections that covers: the premises; storage conditions; stock management; drug labelling; presence of unregistered, banned or expired drugs; documentation on controlled drugs; and retailer knowledge. Every supervisory committee picks a random sample of retail shops to visit quarterly and sends a report of their activities quarterly to the FDA. Every retail pharmacy and wholesaler needs to renew their license every 3 years and for this at least one inspection is needed. If controlled drugs are sold, the license should be renewed annually. While inspection with regard to controlled drugs is always done thoroughly, it is difficult to look at all other aspects in depth, due to the paucity of inspectors and lack of time. Punitive action for contravention of the rules is often not taken, except warnings given to the drug seller from the respective Food and Drug Supervisory Committee with regard to narcotics. One of the pharmacies visited mentioned that some unregistered medicines had been confiscated during an inspection some months previously and that a warning letter had been given that his licence could be withdrawn (though it was not revoked). The pharmacy owner had not realized that the concerned medicines were not registered. Retail pharmacy licenses may be revoked but only with agreement of the central Food and Drug Supervisory Committee. Retail pharmacies also sell traditional medicines but the FDA structure does not review this, as it comes under the remit of the Department of Traditional Medicine. The latter does not issue licenses to sell traditional medicines nor is it clear whether they do any routine inspection of retail pharmacies with regard to traditional medicines.

7.7. Drug Registration

The process of registration remains similar to that operating in 2011. Product registration for old molecules already on the market only requires review of all specifications within a dossier by the FDA, as per ASEAN guidelines. It has been difficult to limit the number of me-too products that are registered and the number of products on the market has risen from 10,300 in 2011 to more than 17,000 in 2014. Twelve product applications for molecules already on the market have been disallowed (paracetamol, sildenafil, tadalafil, cough and cold remedy, ceftriaxone 1g injection, ciprofloxacin and omeprazole). New molecules require a review by the Technical Advisory Committee once information about the product is gathered by FDA staff. New molecules will only be considered for registration if they are already registered in the UK, USA, Australia, Thailand, Indonesia or Singapore. Registration lasts 1-5 years and the registration fee has recently been increased to USD 800 for 5 years, for old and new molecules alike. All revenue is sent to the Treasury.

The Technical Advisory Committee has 22 members including: the DG Department of Food and Drug Administration (FDA); Deputy DG FDA; Director Department of FDA; Deputy DG Medical Care Division DOH; Deputy DGs Medical Research Lower Myanmar and Upper Myanmar; Rector the University of Pharmacy in Yangon; Deputy DG Department of Livestock and Agriculture; Prof and Head of Medicine Department in the University of Medicine I in Yangon and in Mandalay; Prof and Head of Medicine Department University of Defense Services in Yangon; Prof and Heads of Department for Surgery, Obstetrics and Gynaecology, and Paediatrics in the University of Medicine II in Yangon; Professors and Heads of Department for Pharmacology, Anaesthesia, Radiation, Oncology, Medical Oncology, Radiology in Yangon. The committee meets quarterly.

The FDA was aware of the regulatory burden arising from having too many products on the market and had tried to decrease this by stopping loan licenses. This had resulted in some opposition from the pharmaceutical industry that was pushing hard to increase the number of products on the market. The FDA Director General mentioned that fake registration documentation had been found in government hospital tenders.

Registration of TRM products is decided by a separate regulatory committee under the Department of Traditional Medicine.

7.8. Pharmacovigilance

National pharmacovigilance was previously reported in 2011 as being undertaken by the Department of Medical Research. The FDA mentioned that, although they have no specific designated unit to do pharmacovigilance, it was their responsibility and that they have distributed the ADR reporting forms to teaching hospitals, State and Regional Health Offices, and to the Myanmar Medical Council. Unfortunately, no pharmacovigilance was being undertaken since no ADRs had been reported since the last situational analysis in 2011. No hospitals were undertaking any pharmacovigilance.

7.9. Drug Promotion

The Drug Division in the FDA is responsible for the pre-approval of the advertising of OTC medicines and pre-approval for package information inserts for all medicines at the time of registration. No advertising of

prescription-only medicines is allowed. There is some adhoc post-approval monitoring, relying on competitors to inform on their rivals and then asking the University of Medicines I in Yangon to review the concerned advert. There is no dedicated committee to undertake this function. Inappropriate television advertising of vitamins was previously reported but it is not clear whether any action was taken over this. No other monitoring of promotional activities is undertaken. However, some pharmacists have been newly appointed and will be screening and checking all drug advertisements made on TV, radio or in magazines.

7.10. Drug Price controls

The Myanmar Pharmaceutical and Medical Equipment and Entrepreneur Association in collaboration with the Ministry of Commerce decide basic ground prices for imported drugs. It is not clear how the MPF prices are decided. Wholesalers are then allowed a 5-7% mark-up and retailers a further 5% mark-up for vitamins and 10% for other drugs. In remote areas transport fees will also be added. There appears to be little monitoring or supervision of prices charged. The FDA has no role in price setting or monitoring.

7.11. Drug Testing Laboratories

The FDA has its own main Drug Testing Laboratory in Nay Pyi Taw plus a small branch lab in Mandalay and another lab in Yangon which is just starting up. There are SOPs for some procedures, including analytical methods for identification of more than 100 medicines and microbiological assay.

Currently there are 38 technical staff, including 19 pharmacists in the Nay Pyi Taw lab , two technical staff including one pharmacist in the Mandalay lab and one pharmacist in the Yangon lab. There are three departments within the Nay Pyi Taw lab including pharmaceutical chemistry, microbiology and biostandardisation, and pharmacology. The pharmaceutical chemistry lab has tested 127 products and the microbiology lab has done 38 microbiological assays.

About 1000 drug samples are tested per year and about 3-5% of samples fail. In addition, a program of minilabs operating in each state and region to test the quality of anti-malarials has just started and so far 52 samples have been tested in border areas, with 6 samples failing. In addition a Japanese university is testing drug samples collected from Yangon wholesalers.

Traditional medicines (TRM) are tested in a separate laboratory run by the Department of Traditional Medicine. The numbers of samples tested since April 2014 are: 475 registered TRM products, 98 TRM products for quality control certificates, 177 TRM raw materials for importation and 22 TRM products for registration. The failure rate is unknown. Testing traditional medicines for contamination with allopathic medicines is difficult and it is unclear whether the TRM and allopathic laboratories, run by two separate departments in the MOH, coordinate and share expertise.

7.12. Licensing and accreditation of health professionals

The Myanmar Medical Council (MMC) is responsible for licensing doctors, who must renew their licence every 3 years. Myanmar citizens who have graduated abroad must take the licensing exam for a fee of USD 200 and only 40% of persons taking the exam pass. The registration fee is 15000 Kyat and then 10000 Kyat 3-yearly. The medical curricula and final examinations are supervised by the MMC. There are plans to have specialist licenses but this has not started yet. There is no system of accreditation for license renewal. The MMC also investigates a few complaints against doctors per year. The MMC is partially independent of government and there is currently a new law to grant them full independence under parliamentary review.

The Myanmar Medical Association (MMA) is a member-based organization with about 18,000 members – about half the practicing doctors. A member must pay an annual fee of 7,000 Kyats or 10,000 Kyats for life membership. Benefits include a copy of the journal (currently free but fees soon to start) and reduced fees for the annual conference. The MMA is the only fully independent association of doctors. It has specialist societies for all the major specialties, runs CME modules for private practitioners and is drafting clinical guidelines with the Myanmar Academy of Medical Sciences.

The Myanmar Academy of Medical Sciences (MAMS) is a government think-tank to recommend policies to government. All the staff are appointed by government and are mostly retirees from government service. The senior executive officer of the MAMS is a former chief of the FDA. He mentioned that: there were too many brands for the same medicine on the market; drug regulation was weak; MPF has produced good quality essential medicines previously but that their performance was now less good; local manufacturing needs increasing; and that there were too many pharmacy shops which also were not run by pharmacists.

The pharmacists and nurses associations are member-based organizations. However, qualified pharmacists and nurses do not need any individual licence from a pharmacy or nursing council, respectively, or government. Paramedical health workers also do not need a license from the MOH to work, rather the MOH oversees the curriculum and examination of the only university - Magway University – where they can train.

7.13. Licensing and accreditation of health facilities and pharmacies

Pharmacies are licensed by the local Food and Drug Supervisory Committee according to a checklist. However licences can only be revoked by the central Food and Drug Supervisory Committee after consideration of the recommendations of the local committee.

Private health facilities are licensed annually the Medical Care Division of the Department of Health according to a checklist and an inspection.

7.14. Summary status including progress / changes / problems in medicines regulation since last situational analysis

Since 2011 the Myanmar Food and Drug Administration has been upgraded from a Division under the Department of Health to full department under the MOH with its own Director General. This has led to an increase in the number of posts and recruitment is now under way. The pharmaceutical sector continues to grow, with now over 17,000 allopathic drug products registered, 8 manufacturing units, 170 importers/wholesalers and over 10,000 drug retail pharmacies, to be managed by 392 staff. Due to under-staffing and lack of staff capacity the FDA has great difficulty to fulfil all its obligations. The national drug testing laboratory is now testing over 1000 drug samples per year, of which 3-5% fail and a current project is establishing mini-labs in all states and regions. In addition there are 12,000 traditional medicines, all registered for OTC use. Unfortunately post-marketing surveillance is suboptimal and no ADRs have been reported in recent years, drug registration is not stringent enough so allowing too many products on the market, there is no actively used OTC list and monitoring of drug promotional activities is weak.

7.15. Medicines regulation: Recommendations

- Strengthen the Department of the Food and Drug Authority (FDA):
  - Recruit more inspectors and pharmacists – 1 pharmacist per township;
  - Develop Standard Operating Procedures (SOPs) and guidelines for all procedures;
  - Train staff in various regulatory functions including dossier evaluation for drug registration and inspection of manufacturing plants for Good Manufacturing Practice;
  - Amend current regulations to allow more punitive actions (partially done through Amendment of National Drug Law in April 2014).

- Strengthen national laboratory capacity in quality testing of drugs:
  - Establish functional laboratories in Mandalay and Yangon and increase the number of samples tested per year;
  - Expand the minilab system to test more samples and more drugs in every state and region;
  - Develop Standard Operating Procedures (SOPs) and guidelines for all procedures.

- Strengthen post-marketing surveillance:
  - Improve the combatting of illegal substandard, spurious, fake, falsified, counterfeit drugs, particularly in the border areas;
  - Establish a unit to coordinate pharmacovigilance activities and sensitize prescribers to report adverse drug reactions;
  - Start monitoring of drugs prices and consider price controls for essential drugs.

- Establish more drug schedules:
  - Over-the-Counter (OTC) drugs;
  - Drugs for use in tertiary referral hospitals only with availability only from special pharmacies, such as oncological drugs, new antibiotics (such as is currently the case for controlled drugs).

- Strengthen the drug registration process:
  - Have a transparent process with stronger criteria, stricter application of criteria, and review of all products by the technical advisory committee;
  - Will help to reduce an excessive number of products being registered for some molecules.

- Consider establishing a unit to monitor drug promotional activities:
  - Would allow more active monitoring of adverts in the market;
  - Could introduce a requirement for all manufacturers to declare expenses on marketing.

8. MEDICINE POLICY AND COORDINATION

8.1. National Medicines Policy

There is a national drug (medicines) policy (NMP) document 2001 which has 13 objectives covering the areas of:

- Drug supply, availability and affordability
- Rational use of Drugs
- Manufacture of Drugs
- Drug Regulation
- Human Resources for Drug Management
- Adequate financial resources for drug management

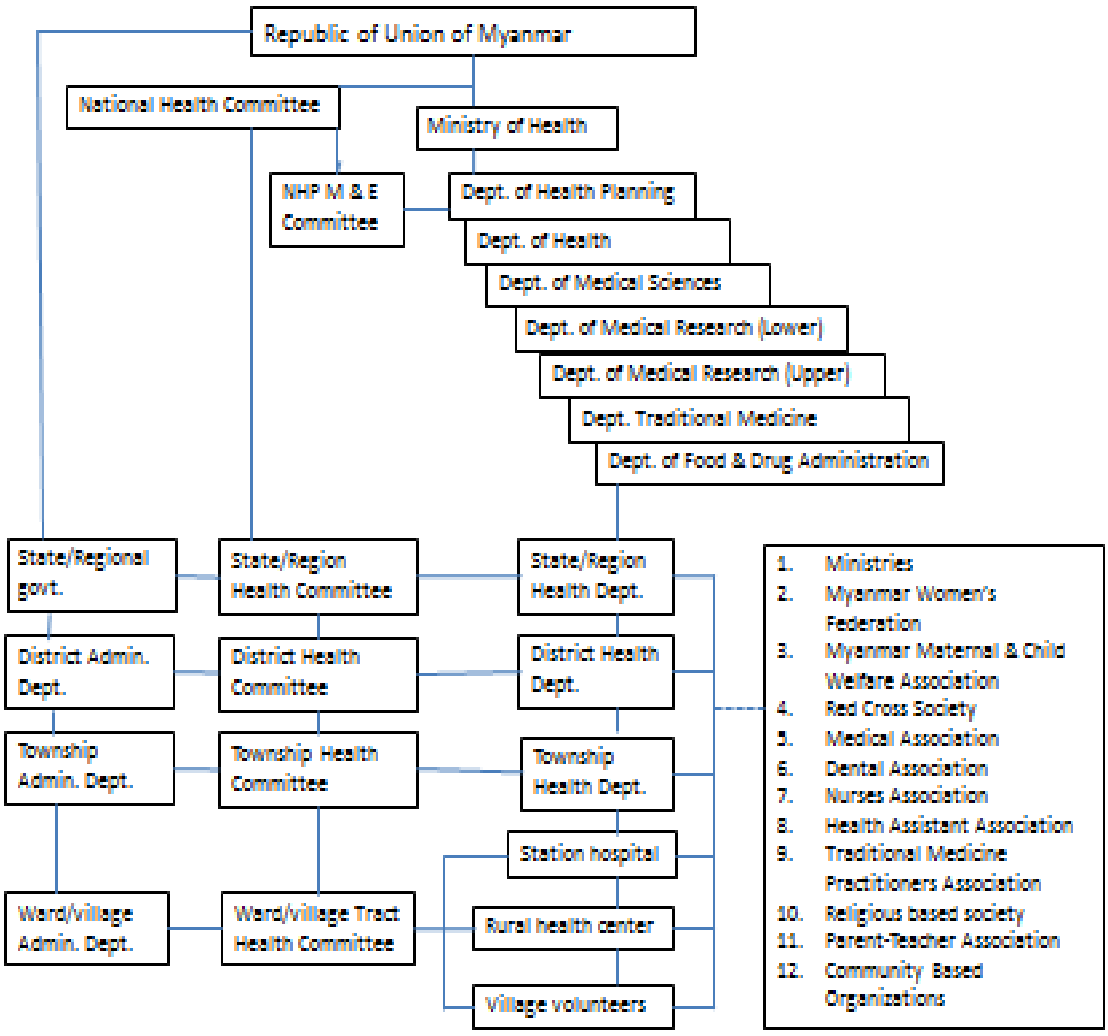
However, the NMP does not have a section on monitoring and evaluation and also lacks details with regard to many of the components. In addition, there is no implementation plan. Many people complained that the NMP was only on paper and nothing was implemented. The current government wishes to update / draft a new NMP.

8.2. Summary of medicines policies in place to promote rational use of medicines

Policy	Implementation status
National Medicines Policy (NMP)	NMP document 2001
National Essential Medicines List (EML)	EML 2010 and revision currently in process
National Standard Treatment Guidelines (STGs)	National STGs for primary care workers, but not for secondary or tertiary care. MMA and MAMS drafting STGs for secondary care
National Formulary manual	Myanmar Pharmaceutical Index produced published by the MMA in 2014 but not national formulary manual published by government
National government unit dedicated to promoting rational use of medicines	No government unit dedicated to promoting rational use of medicines
Monitoring medicines use	No monitoring done
Drug and Therapeutic Committees (DTCs)	No hospital drug and therapeutic committees only purchase committees in hospitals with 200 or more beds
National Drug Information Centre (DIC)	No national drug information centre
Generic Policies	There are no generic policies but generic substitution is allowed in the public and private sectors
Health insurance	None
Payment for medicines by patients	All drugs dispensed free of charge in the public sector. Some cost-sharing fees for diagnostic tests
Provider revenue from medicines	No provider revenue from medicines in the public sector. Some private doctors dispense.
Undergraduate training on pharmacology & prescribing	National EML and STGs are not part of the curricula.
CME training on pharmacology & prescribing	Most CME is adhoc although some is provided by MOH vertical disease control programs to township staff and some is provided by the MMA to private GPs
Public education on medicines use	No public education campaigns on the safe and prudent use of medicines
Pharmacovigilance	Done by the Department of Medical Research and/or FDA but no ADRs reported since 2011
Regulation of drug promotion	Government regulation for the pre-approval of adverts and package inserts for OTC medicines but post-approval monitoring is adhoc and no other monitoring of promotional activities done.
National strategy to contain Antimicrobial Resistance	No national strategy to contain AMR
Over-the-counter availability of prescription-only medicines including antibiotics	Prescription-only medicines easily available OTC.

8.3. Coordination of medicines-related policies within the Ministry of Health

8.3.1. Organization of Health Service Delivery in Myanmar



Source: Health in Myanmar 2014

8.3.2. Coordination within the Ministry of Health

The MOH consists of seven departments each with its own Director General:

- Department of Planning;
- Department of Health;
- Department of Medical Science (which includes the national poisons control centre);
- Department of Food and Drug Administration;
- Department of Traditional Medicine;
- Department of Medical Research – upper Myanmar;
- Department of Medical Research – lower Myanmar.

Within the Department of Health there are 10 divisions:

- Planning;
- Administration;
- Finance;
- Medical Care (which includes EDP, hospital care);
- Public Health (which includes nutrition, school health, MCH, reproductive health);
- Disease Control;
- Central Epidemiological unit;
- Nursing;
- Health Education (which includes public education);
- Occupational and Environmental Health.

The Essential Drug Program (EDP) is a unit of one Deputy Director and one secretary within the Medical Care Division. This unit is responsible for drug supply, selection, use and policy – which is clearly a very large portfolio for a very small team. Divisions with responsibility for medicines include Medical Care and Public Health.

Within the Department of Traditional Medicine (TRM) there are four divisions:

- Administration, which runs the hospitals and clinics;
- Medical Care, which oversees the traditional practitioners;
- Medicines and Herbal Garden, which is in charge of the two government TRM factories;
- Research and Development, which is in charge of regulation and research.

Overall the department employs about 1500 staff of which 75% are TRM practitioners. The DG and Deputy DG of the Department of TRM are medical doctors specializing in public health. There is one TRM officer per state and region.

8.4. Other Ministries with medicines-related functions

Other Ministries involved in medicines-related policies include:

- Ministry of Finance and Treasury – provides budget (which may not be enough) for:
    - human resources employed in all sectors of the MOH;
    - public sector medicines supplied by the CMSD and local drug purchase.

- Ministry of Industry runs the Myanmar Pharmaceutical Factory (MPF) which is not producing the medicines that the MOH wants, nor the quantities of medicines ordered in a timely manner.

- Ministry of Commerce in association with the Myanmar Pharmaceutical Medical Products and Entrepreneur Association sets rules (which may not always serve the public health interest) for:
    - Medicines prices and mark-ups;
    - Duties and taxes on the importation of medicines;
    - The fees for licensing of importer and drug outlets and the ruling that disallows any kind of limitation on the number of drug outlets, particularly retail pharmacy shops;
    - The ruling that disallows any limitation on the registration of medicines.

- Ministry of Education – sets training programs and curricula for some health professionals:
    - May not give the same importance to some topics as would the MOH in determining health service delivery needs.

- Ministry of Planning and Economic Development decides on sanctioned posts based upon proposals submitted by the other ministries including MOH (via the planning division in the DOH):
    - May not assign posts as MOH needs e.g. no extra pharmacists for state and regional health authorities despite the extra need with local medicines procurement, no extra staff for the EDP unit despite the heavy workload.

Coordination between the MOH and other Ministries with regard to pharmaceuticals is sometimes not well managed due to lack of a coordinating unit. In Myanmar, there is the Additional Health Committee, which is chaired by the vice-president, with representation from many Ministries. However, it does not seem to have discussed many pharmaceutical policy issues.

Problem policies, requiring intervention by other ministries, include:

- Excessive number of drug products on the market, resulting in extra regulatory burden, because limits cannot be placed on new products of molecules already existing on the market due to trade rules concerning competition.
- Excessive number of pharmacies in Myanmar, resulting in extra regulatory burden, because limits cannot be placed on new pharmacies due to trade rules concerning competition.
- Lack of pharmacists in the human resource plan, but without them, quantification and efficient procurement sufficiently in advance cannot be done.
- Lack of clinical pharmacology and clinical pharmacy departments and activities in the clinical setting, without which good pharmaceutical care cannot be introduced and which will require coordination between different directorates/departments within the MOH and the Ministry of Education.
- Lack of economies of scale and capacity to ensure quality products are procured in the current decentralized procurement system – which could be rectified by negotiating prices and pre-qualified suppliers centrally for use in local procurement in the public sector.
- Lack of sharing expertise and resources to regulate the sectors of allopathic and traditional medicines – inspecting pharmacy shops, testing for contamination of TRM products with allopathic ones, etc.

8.5. **Summary status including progress / changes / problems** in medicines policy since last situational analysis

The national drug policy, coordination and structure remain similar to the situation in 2011. The FDA has been upgraded and more posts sanctioned but the EDP remains the same. Many objectives of the 2001 national drug policy remain unfulfilled and many policies to promote rational use of medicines and to monitor medicines use are not implemented by any MOH department or unit. There is a high level committee – the Additional Health Committee - which is chaired by the vice-president, with representation from many Ministries, but it does not seem to have discussed many problem pharmaceutical policy issues or the national drug policy.

8.6. Medicines policy and coordination: Recommendations

- Organize high level drug policy discussions in the Additional Health Committee, which is chaired by the vice-president, with representation from many Ministries. Examples of policies for discussion include:
    - Review and clarify the roles of the public (MPF and CMSD) and private sectors in procurement and supply, including what functions should be done centrally (e.g. price negotiation, and prequalification of suppliers and products) and what functions locally by hospitals, regions and states and what extra human (e.g. pharmacists) and financial infrastructure are needed.
    - Review/streamline fiscal requirements with regard to local procurement and auditing. For example, overworked nurses currently have to operate 6 stock books for ward management of drugs.
    - Review the trade rules of competition with regard to licensing of pharmacies and registration of new products for molecules for which there are already many products on the market. Allowing the unlimited licensing of shops and products results in a heavy regulatory burden for the FDA and compromise patient safety.
    - Review the national drug policy and develop an implementation plan and budget.

- Strengthen the Myanmar Essential Medicines Project to be the Executive Division in MOH to implement the decisions of the Additional Health Committee within the MOH:
    - To coordinate action between all MOH divisions and different Ministries;
    - To be responsible for rational use of drugs: EML, STGs, DTCs, monitoring drug use, CME, Drug Information Centre, public education;
    - To liaise with universities to provide students to collect information needed by the MOH, as part of their research studies;
    - To review/update the National Medicines Policy to be more specific and to include an implementation plan, budget and time line.

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10. PERSONS MET DURING THE SITUATIONAL ANALYSIS

	Name	Designation and Affiliation
1	Dr Mya Thaung	Senior Medical Superintendent, North Oakkalapa Tertiary Hospital, Yangon
2	?	Hospital Administrator, North Oakkalapa Tertiary Hospital, Yangon
3	?	Pharmacist, private OPD pharmacy, North Oakkalapa Tertiary Hospital, Yangon
4	Prof Dr Aye Aung	Senior Consultant Physician Obs & Gyane, North Oakkalapa Tertiary Hospital & Vice-President Myanmar Medical Association, Yangon
5	Prof. Thet Khaing Win	Rector, Physician, University of Medicines I, Yangon
6	Prof. Dr Win Myint Oo	Head, Dept of Preventive & Social Medicine, Univ Med 1, Yangon
7	Prof. Dr San San Nwe	Rector, Pharmacology, University of Medicines I, Yangon
8	Prof. Ne Win	Prof. Medicine, Myanmar Medical Council
9	Dr Win Win May	Assoc. Prof. Pharmacology, University of Pharmacy, Yangon
10	?	Lecturer, Dept. Pharmacology, University of Pharmacy, Yangon
11	?	Lecturer, Dept. Pharmacology, University of Pharmacy, Yangon
12	?	Myanmar Academy of Medical Science, Yangon
13	?	Myanmar Academy of Medical Science, Yangon
14	Prof Saw Win	Secretary General and physician in 2 private hospitals (Parami & Bahosi), Yangon
15	Zaw Moe Khine	Myanmar Pharmaceuticals & Medical Equipment Entrepreneurs' Association & Chairman AA Medical Products Ltd. Yangon
16	Dr Aung Gyi Maung	Deputy Director, Central Medical Store Depot, Yangon
17	?	Central Medical Store Depot, Yangon
18	?	Central Medical Store Depot, Yangon
19	Dr Soe Naing	Assistant Director, Central Medical Store Depot, Mandalay
20	Dr Thida Hla	Deputy Director Medical Care, MOH, Nay Pyi Taw
21	Dr Shin Hnaung	Pharmacology Dept. University of Medicines II, Yangon
22	Dr Khin Lin	Deputy Director General, Dept. Medical Research (Upper Myanmar), Nay Pyi Taw
23	Prof Dr Soe Lwin Nyein	Deputy Director General Disease Control, Dept. Health , MOH, Nay Pyi Taw
24	Dr Than Win	Deputy Director General Medical Care, Dept. Health , MOH, Nay Pyi Taw
25	Win Myint	Director Research & Development, Dept. Traditional Medicine, MOH, Nay Pyi Taw
26	Dr Thida Kyu	Director Admin, Dept. Traditional Medicine, MOH, Nay Pyi Taw
27	Prof Myint Han	Director General, Dept. Food & Drug Administration, Nay Pyi Taw
28	Dr Zaw Win	Deputy DG, Dept. Food & Drug Administration, Nay Pyi Taw
29	Dr Khin Chit	Director Laboratory, Dept. Food & Drug Administration, Nay Pyi Taw
30	Dr Thinzar Thike	Asst. Director, Dept. Food & Drug Administration, Nay Pyi Taw

	Name	Designation and Affiliation
31	Dr Su Su Dwe	Medical Superintendent, Pyin Oo Lwin General Hospital, Mandalay region
32	Dr Kyaw Thu	Senior Consultant Physician, Pyin Oo General Lwin Hospital, Mandalay region
33	?	Pharmacist, Pyin Oo Lwin General Hospital, Mandalay region
34	?	Pharmacist, Pyin Oo Lwin General Hospital, Mandalay region
35	?	Medical Superintendent, Mandalay 300-bedded teaching hospital
36	?	Senior Consultant Physician, Mandalay 300-bedded teaching hospital
27	?	Pharmacist, Mandalay 300-bedded teaching hospital
38	?	Pharmacist, Mandalay 300-bedded teaching hospital, private OPD pharmacy
39	Dr Salma Burton	Public Health Administrator, WHO, Yangon
40	?	National Program Officer, WHO, Yangon
41	San San Min	Country Director, SCMS, Management Sciences for Health, Yangon
42	Than Naing Oo	Technical Adviser, , SCMS, Management Sciences for Health, Yangon
43	?	Medical Officer, North Dagon Township Hospital, Yangon
44	?	Compounder, North Dagon Township Hospital, Yangon
45	?	Health Assistant, Sitpin RHC, E. Dagon Township
46	?	Other health worker, Sitpin RHC, E. Dagon Township
47	?	Nurse-midwife, Sham Tac Gyi sub-RHC, E. Dagon Township
48	?	Other health worker, Sham Tac Gyi sub-RHC, E. Dagon Township
49	?	Medical Officer, Patheingyi Township Hospital
50	?	Compounder, Patheingyi Township Hospital
51	?	Health Assistant, Sin Ywar Gyi RHC, Patheingyi Township
52	?	Other health worker, Sin Ywar Gyi RHC, Patheingyi Township
53	?	Nurse-midwife, Kaung Mon Sub-RHC, Patheingyi Township
54	?	Other health worker, Kaung Mon Sub-RHC, Patheingyi Township
55	Pyin Mar Nar	Pharmacy owner, Ko Kyi Soe Pharmacy shop, Nay Pyi Taw
56	?	Pharmacy owner, Seit Ta Thu Kha Pharmacy Shop, Pyin Oo Lwin town
57	?	Pharmacy owner, Phi La Min Pharmacy Shop, Pyin Oo Lwin town
58	?	Medical Officer, North Dagon Township Hospital, Yangon

11. PARTICIPANTS OF THE STAKEHOLDER WORKSHOP

	Name	Designation and Affiliation
1	Dr Win Myint	H.E Deputy Minister of Health
2	Dr Min Than Nyunt	Director General, Department of Health
3	Dr Than Zaw Myint	Director General, Department of Medical Science
4	Dr Myint Han	Director General, Food and Drugs
5	Dr Maung Win	Medical Superintendent, Mandalay General Hospital
6	Dr Than Win	Deputy Director General, Department of Health
7	Dr Khin Win Thet	Director (Medical Care)
8	Dr San San Minn	SCMS (INGO)
9	Dr Mya Thaung	Medical Superintendent, North Okkalar General Hospital (Yangon)
10	Dr Aung Gyi Maung	Deputy Director, CMSD
11	Dr Nang Hla Hla Win	Professor/Head (Pharmaco), University of Medicine 1, Yangon
12	Dr Than Naing Oo	Medical Superintendent, District Hospital, Yamethin Mandalay Township
13	Dr Thin Thin Nwe	Associate Professor (Medicine), Yangon General Hospital
14	Dr Hnin New Ni Aye	Assistant Surgeon, Divisional Health Department, Mandalay
15	Dr Thant Thant Wai	Pediatrician, Minbu General Hospital
16	Dr Kyi Kyi San	Professor/Head (Anesthesia), Yangon General Hospital
17	Dr Than Than Sint	Professor (Radiation), University of Medicine 1, Yangon
18	Dr Myo Myint Maw	Associate Professor/Head, Yangon General Hospital
19	Dr Yi Mon Wint Aung	Assistant Surgeon, Yangon Division
20	Dr L Htoo Pe	Assistant Director, National Health Laboratory
21	Dr Zaw Moe Khine	Secretary, Myanmar Pharmaceuticals and Medical Equipment Enterpreneurs' Association (Private sector)
22	Dr Khin Lin	Deputy Director General, Department of Medical Research (Upper Myanmar)
23	Dr Win Aung	Director, Department of Medical Research (Lower Myanmar)
24	Dr May Thin	Medical Superintendent, 330-bed Hospital, Mandalay
25	Dr Aung Zaw	Deputy Director, Myanma Pharmaceutical Industry, Yangon
26	Dr Win Mar Soe	Lecturer, University of Medicine, Mandalay
27	Dr Phyo Phyo Wai	Assistant Lecturer, University of Medicine, Mandalay
28	Dr Soe Naing	Assistant Director, CMSD (Mandalay Branch)
29	Dr Shin Naung Lwin	Lecturer, University of Medicine II, Yangon
30	Daw Nang Hnisi	Pharmacist, Kalaw, General Hospital
31	Daw Yi Yi Swe	Township Health Assistant, Shan East
32	Daw Khin Thardar Soe	Pharmacist, North Okkalar General Hospital, Yangon
33	Daw Su Hlaing Win	Pharmacist, Pa-an General Hospital, Kayin State
34	Daw Aye Aye Myo	Pharmacist, Mawlamyine General Hospital
35	Dr Thuzar Hlaing	Tavoy General Hospital
36	Dr Phyo Phyo Mon	State Health Officer, Taunggyi, Shan State

	Name	Designation and Affiliation
37	Daw Tin Tin Nwe	Pharmacist, Phyapon General Hospital
38	Daw Mya Mya Thin	Pharmacist, Taunggyi General Hospital
39	Dr Moa Moa Aung	Assistant Lecturer (Medicine), Mandalay General Hospital
40	Dr Khin Thandar Win	Assistant Surgeon (Medicine), Mandalay General Hospital
41	Dr Moe Naing	Lecturer (Medicine), Yangon General Hospital
42	Dr Kyaw Wunna	Specialist (Medicine), Maubin General Hospital
43	Dr Khin Cho Mon	Assistant Surgeon (Medicine), Pa-an General Hospital
44	Dr Than Naing Min	Specialist (Medicine), Hinthata General Hospital
45	Dr Win Aung Kyi	Specialist (Ortho), Yangon General Hospital
46	Dr Aung Thu	Assistant Lecturer (Medicine), Bamo General Hospital
47	Dr Ye Myint Thu	Specialist (Medicine), Loikaw General Hospital
48	Dr Hla Hla Kyi	Health officer, Nay Pyi Taw
49	Daw Lay Nwe	Assistant Officer, Naypyitaw Council Development Committee (Municipal)
50	Dr Kyaw Myint	Medical Superintendent, Pyinmana General Hospital
51	Daw Nilar Theint	Pharmacist, Food and Drugs Administration, Nay Pyi Taw
52	Dr Aung Myo Min	Military Hospital, Nay Pyi Taw
53	Daw Ei Mon	Pharmacist 2, Pyinmana Hospital
54	Dr Win Naing	Director (CEU), Department of Health
55	Daw Nandar Wai	Pharmacist 2, Pharmaco
56	Daw Hnin Wut Mhon	Officer (Drugs), Pyinmana General Hospital
57	Dr Kyaw Zeya Lin	Military Hospital, Nay Pyi Taw
58	Daw Thet Su Nyein	Pharmacist, Leway General Hospital
59	Dr Tin War War Win	Deputy Director, Food and Drugs Administration
60	Dr Khin Chit	Director, Food and Drugs Administration, DOH
61	Dr Moe Swe	Director, Occupational Health, DOH
62	Daw Ohn Mya Mya	Assistant Director, Nursing, DOH
63	Daw Thiri Kyaw Soe	Pharmacist
64	Dr Ye Min Thu	Military Hospital, Nay Pyi Taw
65	Dr Khin Phyu Pyar	Military Hospital, Nay Pyi Taw
66	Dr Khin Than Mon	Assistant Director (Medical Care), DOH
67	Dr Thuzar Chit Tin	Director (Health Promotion), DOH
68	Dr Theingi Myint	Director (Maternal and Child Health), DOH
69	Dr Htay Aung	Deputy Director General, Department of Health
70	Dr Myint Myint Than	Director, DOH
71	Dr Phyu Phyu	Medical Superintendent, Na Pa Ta Hospital
72	Dr Kyaw Shwe	Director, Department of Medical Science

	Name	Designation and Affiliation
73	Dr Soe Soe Min	Nay Pyi Taw City Development Committee
74	Dr Thinzar Htike	Assistant Director, Food and Drugs Administration
75	Dr Ywel Nu Nu Khin	Assistant Director, Medical Care
76	Daw Chaw Phyu Shi	Pharmacist 2, Ottara Thiri Township Hospital
77	Daw Nilar Theint	Pharmacist 2, Poppa Thiri Township Hospital
78	Daw Khin Myat Noe Oo	Pharmacist 2, Poppa Thiri Township Hospital
79	Daw Zin Mi Mi Aung	Pharmacist 2, Dekina Thiri Township Hospital
80	Daw Lay Nwe	Pharmacist 2, Zabu Thiri Township Hospital
81	Daw Nandar Wai	Pharmacist 2, Zayyar Thiri Township Hospital
82	Daw Mya Mya Khet	Pharmacist, Tet Nay Wun Medical Store (Private Sector)
83	Dr Myat Noe Htin Aung Myint	Assistant Surgeon (Medical Care)
84	Dr Chaw Nandi	Assistant Director (Medical Care)
85	Daw Nang Khin Mar Lay	Medical Social Officer, DOH
86	Dr Phone Maw	Medical Superintendent, Na Pa Ta Hospital
87	Daw Myat Myat Soe	Officer (Drugs), Na Pa Ta Hospital
88	Dr Tin Tin Lay	Deputy Director General, Department of Medical Science
89	Dr Nwe Ni Ohn	Director (Planning), DOH
90	Dr Thidar Hla	Deputy Director(Medical Care), DOH
91	Dr Hla Moe	Deputy Director(Medical Care), DOH
92	Dr Win Min Thiri	Assistant Director (Medical Care), DOH
93	Daw Aye Aye Moe	Officer (Drugs), Pyin Ma Na Hospital
94	Daw Mar Mar Wai	Branch Officer (Medical Care)
95	U Toe Toe Win	Branch Clerk (Medical Care)
96	Kathleen Holloway	Regional Adviser Medicines, WHO/SEARO

11. WORKSHOP SLIDE PRESENTATION

Medicines in Health Care Delivery in Myanmar

Situational Analysis: 13-22 October 2014

Dr Kathleen Holloway, WHO/SEARO
Dr Thida Hla, EDP/Dept. of Health/MOH
Dr Soe Naing, CMSSD/Mandalay
Dr Shin Hnaung, Pharmacology/Univ. of Med II, Yangon
Dr Thinzar Theik, FDA Dept., MOH

Agenda of the workshop

Morning session

- Presentation by situational analysis team with discussion of findings, identification of main problems and possible solutions
- Group work to discuss solutions and develop recommendations to implement solutions
  - include main activities, who will do them, and in what time frame

Afternoon session

- Presentation of group work with plenary discussion and finalization of recommendations
  - Road map for MOH, stakeholders and WHO to follow

Terms of Reference

- To conduct a rapid assessment of medicines in health care delivery covering drug supply, selection, use, regulation and policy,
  - In liaison with national counterparts nominated by the MOH;
  - Taking into account progress made since the last situational analysis done in 2011
- To report on the findings and develop an action plan in a workshop of government officials and other stakeholders.

Mission 13-22 October, 2014

- **13 Oct:** Myanmar team meeting & discussion; visits to WHO country office and N.Okalapa Tertiary Hospital, Yangon.
- **14 Oct:** visits to University of Medicines I (Pharmacology) Yangon; Myanmar Medical Association; Myanmar Academy of Medical Science; CMSD Yangon
- **15 Oct:** visits to University of Pharmacy Yangon; North Dagon Township Hospital & nearby RHC, Sub-RHC in East Dagon township
- **16 Oct:** visits to Dept. of Health; Dept. of Traditional Medicines, Nay Pyi Taw
- **17 Oct:** visits to Mandalay Regional Health Dept.; Mandalay 300-bedded teaching hospital; CMSSD Mandalay
- **18 Oct:** visits to Pyin Oo Lwin general hospital & 2 nearby private pharmacies
- **19 Oct:** visits to Patheingyi Township Hospital & nearby RHC, Sub-RHC
- **20 Oct:** Preparation for the workshop
- **21 Oct:** visits to Food & Drug Administration Dept.; private pharmacy in Nay Pyi Taw

Objectives of the workshop

- Review the situational analysis findings
- Identify the main priority problems to be addressed, in 5 areas:
  - Drug supply, Drug selection, Drug use, Drug regulation, Drug policy
- Formulate recommendations to resolve / address the priority problems in each area
- Develop an action plan to implement recommendations
  - What activity?
  - Who will do it?
  - Timeline?

Mission findings

- Extensive health care system, with substantial infrastructure, trained hardworking health care personnel, and…
- Some areas of progress since last situational analysis in 2011, but some serious problems remain in all areas of drug management
- Some problems can be addressed by existing resources and capacity and others need substantial coordinated effort by all partners.

Drug supply

- **Situational analysis 2014**
  - Government drug expenditure approx. 3 USD/person/year
  - Drugs supplied to health facilities by govt. according to an allocated budget decided by MOH (initially 15 lakhs Kyat/bed/year)
  - Some EDL drugs supplied by "central push system" from CMSD
  - Many drugs (EDL and non-EDL) locally purchased with "pull system"
  - Doctors seeing about 30 out-patients/day in most health facilities
- **Situational analysis 2011**
  - Government drug expenditure < 0.2 USD/person/year
  - Drugs supplied only by "central push system" from CMSD
  - Most supplies lasted 1 month or less & reserved for the poor
  - Doctors seeing about 10 out-patients/day in most health facilities

Stock management

- All drug supply manual, no electronic LMIS system
  - Difficult to assess stock condition re stock-outs and expiry
- Double book keeping for CMSD and local purchase
  - 2 stock books in the main hospital store
  - 6 stock books in each ward for "main store" (room in the ward), "sub-store" (cupboard in nurses station) and "daily store" (trolley)
- Stock books, bin cards, etc. often well maintained
- Pharmacists in 3º hospitals but not in township hospitals or below, where storekeepers, compounders, nurses manage stock
  - Only 15% pharmacists trained in Myanmar find public sector jobs
- Drug procurement and ordering biannual
- Drug quantification adhoc based on limited past consumption data
- Some health facility stores have inadequate space, shelving, temperature & humidity control

Drug availability

- **Situational analysis 2014**
  - Few complaints of stock-out
  - Availability of 22 key EDL drugs (covering CDs/NCDs)
    - 58-92% in tertiary hospitals & township hospitals
    - 49-75% in rural health centres & sub-centres
  - Non-availability mostly due to non-use / non-purchase
  - Most prescribed drugs dispensed but some tertiary hospitals in Yangon only supply OPD drugs through private pharmacy in hospital compound
- **Situational analysis 2011**
  - Many complaints of stock-out
  - Most patients buying drugs from private pharmacies
  - Some health workers bought drugs from pharmacies to sell to patients in health facilities where there is no pharmacy

Drug Supply: recommendations

- Establish harmonised, functional, electronic drug management information system, to monitor consumption, stock-out, expiry which is necessary to improve quantification
  - start centrally/regionally & then extend to district/township level
  - employ a data-entry staff for this purpose at each hospital & district/township
- Employ at least one pharmacist in stock management at regional health offices and district/township hospitals
- Train staff in monitoring medicine consumption and quantification
- Develop policies to better manage drugs and contain costs in the new decentralised procurement system
  - Review double book-keeping system and ward management of drugs
  - Consider central pooled procurement with regard to price negotiation, and prequalification of suppliers and products
  - Clarify the roles of CMSD and MPF in central procurement/supply

Drug procurement

- All State/Regional health departments, tertiary hospitals (>200 beds) and CMSD undertaking purchase
- No economies of scale
  - All purchases from wholesalers, importers & none from manufacturers (except MPF)
  - All purchase in Kyats and 6-monthly, not annually
- No pharmacist in some regional health departments to manage the tendering process
- Government tendering form used, with 2-envelope system
  - One envelope with technical criteria and the other with price
  - Technical criteria include national registration of the product and supplier, 2 years shelf-life, delivery time, replacement of poor/damaged goods, provision of package inserts, GMP cert.
  - Limited capacity to apply/enforce technical criteria in States & Regions

Drug selection

- **National EML 2010**
  - 341 drugs divided into Essential and Complementary drugs
  - Drugs divided into those for tertiary referral level and other levels
  - No distinction between drugs for sub-RHC, RHC & township hospital (although distinguished by level in previous edition 2002)
  - Some prescribing of tertiary level drugs at township level e.g. levofloxacin, losartan
- **Implementation of EDL in 2014**
  - Review of purchase lists: % non-EDL drugs is 21-39% in tertiary hospital lists and 9-23% in other facility lists
  - OPD prescribing survey: 11-25% drugs prescribed are non-EDL
  - Some prescribing of non-EDL drugs at RHCs and sub-RHCs e.g. ampiclox, flumox
  - Drug selection is based on the recommendations of heads of clinical departments in hospitals, no hospital formularies observed

Top drugs by value supplied by NOGH in 2013

	Drug name	Kyat		Drug name	Kyat
1	Amox + Clav 1.2g inj	89,460,000	13	Streptokinase inj	13,400,000
2	Cefperazone+Sulbact 1g	39,200,000	14	Dobutamine 250mg inj	12,756,000
3	Amox+Fluclox 500mg inj	36,400,000	15	Tramadol 100mg inj	11,900,000
4	Normal Saline 500ml IV	29,400,000	16	Metronidazole inj	11,480,000
5	Levofloxacin 500mg inj	23,400,000	17	Vecuronium 4mg inj	10,800,000
6	Ceftriazone 1g inj	18,850,000	18	Imipenam+Cilastatin inj	10,545,000
7	Amox + Clav 625mg cap	16,785,000	19	Dextrosaline 500 ml IV	10,290,000
8	Omeprazole 40mg inj	15,520,000	20	Ringer Lact 500ml IV	10,045,000
9	Ceftazidine 1g inj	15,300,000	21	Cefotaxime 1g inj	9,715,000
10	Amox+Fluclox cap	15,120,000	22	Cefixime 200mg cap	9,676,000
11	Ceftriax+Sulbact 1.5g inj	14,450,000	23	Anti Tetanus Toxoid inj	8,330,000
12	Propofol 20ml inj	13,511,630	24	Zolendronic Acid inj	81,00,000

Top 24 (10%) items cost 58% budget. ABs cost 47%, vits 1%, non-EDLs 29%

Drug use (1)

- No routine monitoring of drug use or prescription audit
  - Hospital Pharmacists could do this and report to DTCs
- No hospital Drug & Therapeutic Committees (DTCs)
  - Only procurement committees
  - Should be a requirement for accreditation for teaching hosp status
  - Set drug policy, monitor ADRs, monitor use, encourage CME, etc
- National Standard Treatment Guidelines (STGs)
  - Available for basic health workers but not for other cadres
  - Myanmar Academy of Medical Science has developed STGs for paediatrics and is developing STGs for medicine, surgery, obstetrics & gynae but will these be adopted by MOH?
- Independent drug information
  - no national Drug Information Centre
  - frequent pharma rep visits to private facilities & referral hospitals

Top drugs by value supplied by CMSD in 2013

	Drug name	Kyat		Drug name	Kyat
1	Anti Rabies Vaccine	2,429,800,000	13	N/Saline IV 500ml	217,800,000
2	OC Pills	2,142,000,000	14	Gentamycin Inj: 80 mg	208,000,000
3	Depo provera inj	1,105,228,800	15	5% Dextrose IV 500ml	198,000,000
4	Ceftriaxone inj:1G	1,040,000,000	16	Clindamycin 150mg	194,000,000
5	Amoxy/Clav 375mg	961,640,000	17	Tranexamic Acid inj	192,004,000
6	Cefotaxime inj:1G	933,600,000	18	D/saline IV 500ml	189,000,000
7	Anti Snake Venom	816,000,000	19	Sulbact/Cefopyrazone	176,561,000
8	Fluclox Cap: 250mg	597,500,000	20	Genta Eye/Ear Drops	175,009,000
9	Mannitol IV 200ml	585,000,000	21	EFV 600mg	173,320,000
10	Water for Inj	351,600,000	22	Omeprazole 20 mg	156,000,000
11	Misoprosol	296,000,000	23	Ringer Lactate 500ml	148,500,000
12	Cycloserine 250mg	257,256,000	24	Lincomycin 500mg	142,500,000

Top 24 (21%) items cost 82% budget . ABs cost 32%, vits 1%, non-EDLs 9%

Drug use (2)

- Prescribing taught at medical undergrad pre-clinical level in the 3rd year but not in the 4th and 5th years
  - Pharmacology/prescribing knowledge undermined by clinical studies and later work
- Post graduate training
  - No clinical pharmacology or clinical pharmacy yet
- CME regular for most govt staff but not much on prescribing
  - MOH program generally for government staff
  - MMA CME training courses for private GPs
- No nationwide public education campaign on medicines use
- Workload
  - Doctors generally see about 30 patients / day
  - Nurses often have to look after 10 or more inpatients each in large hospitals and this is one reason given for not using individual patient dispensing record sheets

Drug Selection: recommendations

- **Revise the EDL (in process):**
  - include drugs for all levels of care
  - classify each drug according to level of care, therapeutic class
  - have wide representation of specialists, generalists & pharmacists, and transparent process to improve acceptance
- **Implement the revised EDL**
  - Consider policy to ensure that most local procurement (e.g. 80% at tertiary level and 90% at township level) consists of EDL drugs
  - Ensure all providers are sensitized/trained on the EDL
  - Monitor compliance
- **Establish a transparent system to review all requests for non-EDL drugs**
  - Drug & Therapeutic Committee in each district hospital and above could consider such requests

Drug use indicator survey 2014

Drug use indicator	Referral hosp n=3	Township hosp n=2	RHC / sub-centre n=4	Drug Retailer n=3
Av.no.drugs/patient	3.3	3.2	2.2	2.2
% patients with ABs	34.3	43.9	53.3	16.9
% patients with INJs	33.2	27.5	7.6	8.3
% patients with VITs	38.9	56.8	41.0	22.8
% generic drugs	53.7	67.4	72.6	25.6
% EML drugs	74.9	89.4	84.2	53.9
% URTI given ABs	73.4	85.7	92.2	-
Av.cost/Px (Kyats)	5,596	-	-	5,180

Number of drugs per patient, antibiotic & vitamin use increased since 2011

Health worker views

- **Medical Superintendent**
  - *The situation with regard to medicines availability is much better since local purchase started*
- **Senior Policy Maker**
  - *We urgently need national standard treatment guidelines to ensure that drugs are used properly and not wasted*
- **Specialist physician**
  - *The nurses are too busy to sign for each dose of drug dispensed on an in-patient record sheet*
- **Nurse**
  - *Six stock books for ward drugs is very time consuming and difficult to manage and we have to store medicines in different places for lack of space*

Drug regulation (1)

- **Food & Drug Administration Dept. (FDA) executes:**
  - National Drug Law 1992 and Amendment April 2014
- **FDA under-resourced**
  - Has >300 staff, 50% technical, (aiming for 624 sanctioned posts)
  - Now recruiting new staff
- **FDA manages a sector consisting of:**
  - About 17,000 Products 8 manufacturing units
  - 170 importers >10,000 wholesalers & retail shops
- **National Drug Control Laboratories**
  - 3 labs with 38 technical staff,
  - About 1000 samples tested per year – 3-5% failed in 2013
- **SOPs/Checklists**
  - ASEAN common technical dossier for registration (ACTD), checklists for outlet inspections, SOPs for drug testing lab
- **40 Prosecutions in 2013**

Drug use: recommendations (1)

- **Monitor drug use**
  - Prescription audit using diagnosis
  - Ensure all out-patient registers have diagnosis & drugs recorded
  - Identify specific inappropriate practices that you want to change (e.g. overuse of antibiotics in upper respiratory tract infection) in order to target interventions to these practices
  - Should be done by all teaching hospitals & regional health offices
- **Review hospital in-patient dispensing procedures**
  - Develop a printed form in which the nurse must sign for each dose of each medicine given, as used in Pyin Oo Lwin general hospital
- **Establish Hospital Drug & Therapeutic Committees**
  - Require them to monitor drug use, encourage CME, and report annually on activities to MOH
  - Pharmacists can act as secretaries & implement DTC decisions

Drug regulation (2)

- **Outlet inspections**
  - About 100 retail & wholesale pharmacies inspections by township Food & Drug Supervisory Committee
  - About 8 manufacturing unit inspections (1/unit/year)
- **Drug Schedules**
  - All drugs apart from controlled drugs available OTC often dispensed by unqualified shop assistants
- **Monitoring of drug promotion**
  - Pre-approval of adverts & package inserts for 'OTC' drugs only but no separate dedicated committee
- **Adverse Drug Reaction Monitoring**
  - 3-4 ADRs reported in 2011, but no ADRs reported to FDA since
- **Drug Price Controls**
  - Prices set by manufacturers in agreement with Min. Commerce & Myanmar Pharm & Med Equip Entrepreneur Assoc. with 5-10% mark-ups in Yangon according to what market will bear

Drug use: recommendations (2)

- **Develop National Standard Treatment Guidelines**
  - To cover secondary as well as basic primary care
  - Incorporate MAMS activities to develop STGs,
  - Disseminate to every doctor & incorporate into CME & UG education
- **Establish a national drug information centre**
  - To provide prescribers with independent information
- **Continuing professional development (CME)**
  - MMA & MMC to develop credit system for CME,
  - Incorporate prescription audit & feedback and ethics into CME
  - Develop clinical pharmacology and clinical pharmacy
- **Public Education Campaign on prudent drug use**
  - Core pharmaceutical messages e.g. *Antibiotics not needed for simple coughs & colds* through Community Midwives and media

Drug regulation: recommendations

- **Strengthen the FDA**
  - More inspectors & pharmacists – 1 pharmacist per township
  - Standard operating procedures and guidelines for all procedures
  - Amend current regulations to allow more punitive actions
- **Strengthen the drug registration process**
  - Stronger criteria e.g. bioequivalence, studies, dissolution profiles, stability studies, with stricter application of criteria
  - Ensure all products are reviewed by the technical advisory committee & make process more transparent
  - Will help to reduce the number of products registered
- **Establish more drug schedules**
  - (1) OTC drugs and (2) drugs for use in tertiary referral hospitals only (special pharmacies) e.g. oncological drugs, new antibiotics
- **Strengthen national control laboratory**
- **Start units to monitor (1) drug promotion & (2) ADRs**

National Drug Policy 2001

13 objectives covering:

- Drug supply, availability and affordability
- Essential drugs and drug selection
- Rational use of drugs
- Manufacture of drugs
- Drug Regulation
- Human resources for drug management
- Adequate financial resources for drug management

BUT

- No implementation plan, executive unit or budget for monitoring implementation of national drug policy

Coordination and management

- **MOH Structure:**
  - 7 depts - DOH, FDA, Trad. Med, Planning, 2 Research, Med Science
  - 10 divisions in DOH, including Medical Care
  - Essential Drug Program (EDP) under Medical Care & has only 1 medical and 1 clerical staff but needs >2 pharmacists
- **Drug policy 2001 comprehensive but old and inadequately implemented**
  - implementation done mainly by EDP & FDA, both under-resourced
- **NDP implementation requires coordination of policy**
  - Which unit in MOH can coordinate between different departments & divisions in MOH and different Ministries and stakeholders?
  - Min Educ (school curricula); Min Finance (drug budget); civil service commission (pharmacy posts); Min Commerce (prices of drug imports); Min Industry (Manufacturers); Dept Medical Science/MOH (training of doctors/pharmacists)

Implementation of NDP

- **Access to essential drugs improved in public sector**
  - increase in govt. budget from 0.2 USD to 3 USD /person /year, but
  - policies needed to contain costs e.g. central negotiation of prices and use of prequalified manufacturers/products
  - investment needed in infrastructure (human resources, electronic LMIS) to manage drugs
- **EDL old and increasingly not followed**
  - EDL needs revision (in process) & policies formed to ensure its use
- **Irrational use of medicines continues**
  - Need to monitor use and implement policies to improve use, which will require a strong coordinating unit in MOH – EDP?
- **Regulation capacity strengthened but still weak**
  - Need to strengthen the MFDA and National Control Lab
- **Government manufacturing is weak**
  - Cannot produce drugs (old/new) needed in quantities required, on time

Coordinating structure and national policy: recommendations

- **Permanent statutory committee to advise the Minister of Health on Pharmaceuticals with wide membership incl. laypersons, professional bodies …**
- **Strengthen the MEMP to be the Executive Division in MOH to carry out the statutory committee recommendations**
  - To coordinate action between all MOH divisions and different Ministries
  - To be responsible for rational use of drugs: EML, STGs, DTCs, monitoring drug use, CME, Drug Info Centre, public education
  - Could liaise with universities to provide students to collect information needed by the MOH as part of their research studies
  - To review/update National Medicines Policy to be more specific & to include an implementation plan, budget and time line

Human resources

- **Adequate numbers of clinical doctors, nurses and paramedical health workers, but**
  - Some redistribution may be needed to ensure more equal workload e.g. nurses in big hospitals are sometimes overloaded while others in smaller units are underworked
- **Inadequate number of pharmacists:**
  - Insufficient numbers of pharmacists employed in public sector – only 15% pharmacy graduates find a post in public sector
  - Pharmacy curricula do not include very much on clinical pharmacy, drug use monitoring or DTCs and there are no faculties of clinical pharmacology or clinical pharmacy yet
  - Stock management at district/township level & below done by nurses, compounders and store keepers
  - Pharmacists can improve drug procurement, supply, distribution, undertake drug use monitoring, drug use evaluation, and participate in DTCs

Group work

- Each group to draft 3-5 recommendations with practical steps including
  - What will you do?
  - Who will do it?
  - In what time line?
- Groups
  - Drug supply
  - Drug selection
  - Promoting rational drug use
  - Drug regulation
  - National structure and drug policy